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PROCESS PATENTS

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TUESDAY, MAY 1, 2007

U.S. SENATE,
COMMITTEE ON THE JUDICIARY,
Washington, D.C.

The Committee met, pursuant to notice, at 2:43 p.m., in room SD–226, Dirksen Senate Office Building, Hon. Patrick J. Leahy, Chairman of the Committee, presiding.

Present: Senators Leahy, Cardin, Whitehouse, Specter, Graham, and Coburn.

OPENING STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM THE STATE OF VERMONT

Chairman LEAHY. I would like to apologize to the four of you, and especially to Senator Specter and Senator Coburn, for being late. I have actually been in the Agriculture Committee, which was running somewhat behind, and everything has been running behind today with the funeral of our good friend, Jack Valenti. Senator Specter and I were both at that earlier today.

I joined with Senator Hatch and other Senators, and with Chairman Berman and Representative Smith from the House Judiciary Committee, just a few weeks ago to introduce sweeping bipartisan, bicameral patent reform legislation. We are trying to update our patent laws to provide help to patent seekers and patent holders. The Supreme Court is also more engaged in patent law decisions than it has been in decades. It has decided three important cases already this term. In two decisions released just yesterday, the Supreme Court ventured, first, into the fundamental issue of the standard for "obviousness" that would prevent patentability and, second, spoke to the extraterritorial effect of U.S. patent laws.

We have heard a great deal about another issue involving U.S. patents and overseas manufacturing—the issues surrounding products produced overseas using processes patented in the United States. One of those issues is the importation of these products. So we will turn today about what defenses should be available to a party accused of importing products manufactured abroad by infringing a U.S. process patent, the so-called 271(g) question.

Sometimes litigation brings important issues to our attention. It should always be the case that we do not intend to interfere with that litigation. We are well aware that private parties are interested, and we will proceed carefully today.

Prior to Congress' amending the patent laws in 1988, a company holding a U.S. process patent could sue for infringement of that patent only if the infringement took place within the United States.

If it took place overseas, they only had the International Trade Commission. In 1988, we amended that law.

The ITC has held that our 271(g) defenses are not available in ITC exclusion proceedings because the plain language of the statute, confirmed by its history, applies them only to patent infringement claims being considered in Federal court pursuant to the 1988 amendment. So we will decide whether this distinction should remain.

I have heard from those who argue that the defenses were never intended to be limited to infringement claims, and the law should be changed to harmonize ITC and district court litigation. Others argue that the purpose of an ITC exclusion proceeding and district court patent infringement litigation are simply different. But if we permit products to enter the United States that were made abroad by a process patented here—where the creation of the product would itself be an act of infringement if it occurred here—well, then, we are doing nothing less than offshoring infringement and outsourcing jobs.

This may seem like is a very narrow legal issue, but the policy can have a very wide reach, and I think we should be fully informed. So I am looking forward to the witnesses today. But before we begin, of course, I yield to Senator Specter.

[The prepared statement of Senator Leahy appears as a submission for the record.]

STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF PENNSYLVANIA

Senator SPECTER. Thank you, Mr. Chairman. This is a very important hearing focusing on a very narrow issue, as you have stated, whether the defenses ought to be available in the International Trade Commission contrasted with the Federal court. And this is part of a broader picture of patent reform where we are deeply involved at the present time, and there is a great deal of thought being given to the whole field, and especially to this specific issue.

I regret that I cannot stay. We are in the midst of a whole series of meetings on immigration reform. We are trying to craft a bill to come before the Senate in the last 2 weeks of this month if we are to have any chance to deal with immigration this year, because once we pass Memorial Day, we get involved in the appropriations process. So there have been very heavy efforts on that, and there had previously been scheduled a meeting at 3 o'clock today, which I am hosting. But my staff is here, and my cerebrum will be here. My cerebellum is going to Hart 711. And the third part of my brain, medulla oblongata, is unoccupied at the moment.

[Laughter.]

Chairman LEAHY. Can I borrow it?

Senator SPECTER. So it is a rest period for part of me. But as I say, my staff will be here, and I will be watching the proceedings very closely.

I have talked to the combatants. This is a Herculean struggle, and we will listen carefully and try to come to a sound legislative judgment. We will try to change our spots and do it rationally.

Chairman LEAHY. Thank you. If you are going to immigration, you are going to another Herculean battle, and I wish you well.

Senator SPECTER. Well, the only regret I have about going to immigration is that I am not taking Coburn and Leahy with me.

Thank you.

Chairman LEAHY. Gentlemen, would you please stand and raise your right hand? Do you solemnly swear that the testimony you will give in this matter will be the truth, the whole truth, and nothing but the truth, so help you God?

Mr. HERRINGTON. I do.

Mr. THOMAS. I do.

Mr. KIRK. I do.

Mr. COTROPIA. I do.

Chairman LEAHY. Thank you. Our first witness will be Wayne Herrington, who is Assistant General Counsel at the United States International Trade Commission. After he got his law degree from Columbia University, he clerked for Judge Giles S. Rich of the U.S. Court of Appeals for the Federal Circuit. I knew Judge Rich. Mr. Herrington then held jobs both with the Government and in the private sector. He is co-author of the book "Intellectual Property Rights and United States International Law."

We will begin with you, Mr. Herrington.

STATEMENT OF WAYNE W. HERRINGTON, ASSISTANT GENERAL COUNSEL, U.S. INTERNATIONAL TRADE COMMISSION, WASHINGTON, D.C.

Mr. HERRINGTON. Thank you. Good afternoon, Chairman Leahy, Ranking Member Specter, and members of the Committee. The Commission appreciates the opportunity to appear before this Committee to discuss its administration of Section 337 of the Tariff Act of 1930 and process patents.

The Commission is an independent, nonpartisan, quasi-judicial agency. It administers a wide variety of trade-related statutes, including Section 337 of the Tariff Act of 1930. Section 337 prohibits unfair practices in the import trade, including imports which infringe intellectual property rights. In fact, the overwhelming majority of our cases under Section 337 involve allegations of patent or trademark infringement, with allegations of patent infringement predominating. We conduct our Section 337 proceedings under the adjudicative provisions of the Administrative Procedure Act, with an administrative law judge making an initial determination and the Commission making the final determination. If the Commission finds a violation of Section 337, it may issue an order excluding the infringing products from entry into the United States. It may also issue cease and desist orders to infringing firms and persons prohibiting them from selling infringing goods already located in the United States.

The subject of this hearing is the law applicable to the unauthorized importation and sale of products made abroad by a process covered by the claims of a United States patent. The Commission has had statutory authority to address such unauthorized importation since 1940, when Congress enacted what used to be known as Section 337a. Section 337a was eventually incorporated in Section 337 itself as Section 337(a)(1)(B)(ii) as a result of the amendments to Section 337 in the Omnibus Trade and Competitiveness Act of 1988.

The current version of that provision provides that the importation, sale for importation, or sale within the United States after importation of a product will be a violation of Section 337 if it is "made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent."

The U.S. district courts did not obtain statutory authority under the patent law to address the unauthorized importation and sale of products made abroad by a patented process until 1988, when 35 U.S.C. 271(g) was added to the patent law by the Process Patent Amendments Act. Besides providing for infringement, Section 271(g) provides that "[a] product which is made by a patented process will, for purposes of this title, not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product."

In 2002, in the Abrasives case, the Commission affirmed an order of one of its administrative law judges that the defenses to infringement contained in 35 U.S.C. 271(g)—that is, 271(g)(1) and (g)(2)—were not available in a case based on the Commission's process patent provision. Specifically, the Commission found that Section 9006(c) of the Process Patent Amendments Act made it clear that the defenses of Section 271(g)(1) and (2) would not apply to Section 337 cases. As an additional reason, the Commission found that Section 271(g) explicitly restricted its application to cases under Title 35. Section 337 is under Title 19.

The accused infringer in the Abrasives case, Kinik, Co., appealed the Commission's final determination to the Federal Circuit, arguing numerous points, including that the Commission erred in holding that Kinik could not rely on the defenses in 271(g)(1) and (2). On appeal, the Federal Circuit agreed with the Commission's interpretation of the statutory provisions and the legislative history with respect to the inapplicability of those defenses. The case is *Kinik Company* v. *International Trade Commission*, a 2004 decision of the Federal Circuit. However, the court reversed the Commission's finding of infringement on an entirely unrelated basis because it disagreed with the Commission's claim construction.

The foregoing is a summary of the Commission's practice and the development of the law. The Commission would be pleased to provide technical advice on legislative language the Committee may be considering.

Thank you.

[The prepared statement of Mr. Herrington appears as a submission for the record.]

Chairman LEAHY. Thank you very much.

Our next witness is John R. Thomas, a professor of law at my alma mater, Georgetown, where he teaches classes on patent law and intellectual property and world trade. He recently received a grant from the MacArthur Foundation—congratulations—in order to continue working as a visiting scholar at the Congressional Research Service. Professor Thomas is an author of several books on intellectual property law and patent law and pharmaceutical patent law.

And I will also take this moment to do some housekeeping and put a statement from Senator Feinstein and a letter from the AFL–CIO in the record at this place.

Go ahead, Professor Thomas.

STATEMENT OF JOHN R. THOMAS, PROFESSOR OF LAW, GEORGETOWN UNIVERSITY LAW CENTER, WASHINGTON, D.C.

Mr. THOMAS. Thank you, Mr. Chairman.

Chairman Leahy, Ranking Member Specter, and other members of the Committee, I appreciate the opportunity to appear before you today. I testify here on my own behalf, and my views are not necessarily those of any institution with which I am associated.

The issue of process patent enforcement is complex. Yet in the view of many observers, the question of process patent enforcement reduces to an elemental proposition of a just system of laws: that like cases should be decided alike, regardless of the forum in which the case is heard.

Competing views certainly exist, and I will rely upon Mr. Kirk to articulate them effectively, but let me focus my testimony instead on the concerns that have arisen with respect to the *Kinik* case and its consequences.

The *Kinik* opinion has attracted criticism for several reasons. First, its holding is purely dicta. It is hastily considered and not necessarily the result of the dispute before the court.

Second, the Federal Circuit arguably misinterpreted language from the statute and legislative history that it read to say that the limitations in 271(g) do not apply to the ITC. But a sensible and alternative reading of that language is merely that 271(g) does not affect wholly domestic situations involving process patents, and that the ITC is not usurped by the availability of a similar remedy in the trial courts.

Finally, the Federal Circuit did not account for the strong presumption against extraterritorial application of U.S. laws. Mr. Leahy, you referenced the *Microsoft* v. *AT&T* case that came out yesterday. There the Supreme Court emphasized that the presumption that U.S. law governs domestically but does not rule the world applies with particular force to patent law. The court further explained that this presumption is not defeated even with respect to provisions like 271(g) that have some extraterritorial effect. In those cases, the presumption remains instructive as to the extent of the statutory exemption. Application of this presumption suggests that the 271(g) defenses should apply not just to the district courts, but also to the ITC.

Now, regardless of whether the Federal Circuit got it right in *Kinik*, there are a number of concerns that its outcome has raised.

First, Congress intended the two exemptions of the Process Patent Amendments Act to balance the traditional competing objectives of patent law, and one of them is to encourage the labors that lead to innovation, but the other is to disseminate the fruits of those labors to members of the public. The "materially changed" and "nonessential component" limitations both balance the interests of patent proprietors, on one hand, with follow-on innovators, and they also recognize the territorial limitations of the patent instrument. These congressional intentions, this balance, simply can-

not be achieved if, at whim, the patent holders can simply go to another forum and bypass them.

Second, our current fragmented enforcement policy may limit the access of U.S. consumers to innovative products that bear a tangential relationship to the patented process. The two exemptions in 271(g) evidence a Congressional intent not to provide patent holders in the United States with an extraterritorial proprietary interest on products too distant from the marketplace value of the patented process. Again, that goal cannot be achieved if a plaintiff on its whim can simply bypass the forum in which they apply.

Finally, the remedial disparity between the district courts and the ITC potentially favors domestic industry over foreign firms. Because the availability of exclusion orders is premised upon the existence of a domestic industry, U.S.-based firms are favored over importers. Although the analysis of whether this regime is effectively a violation of our WTO agreements which bind us is a complex issue, but the perceived favoritism of U.S. industry over foreign firms may send a conflicting message.

Also issued yesterday was the U.S. Trade Representative's report about intellectual property rights in foreign firms, the special 301 report, and the USTR faulted no fewer than 43 of our trading partners for violations or lapses, perceived lapses in intellectual property policy. The U.S. may be subject to similar criticism so long as it maintains a regime of substantive patent law that favors domestic industry over foreign firms.

Thank you very much for the opportunity to present this testimony, Mr. Chairman. I look forward to any questions that you or your colleagues may have.

[The prepared statement of Mr. Thomas appears as a submission for the record.]

Chairman LEAHY. Thank you, Professor, and thank you for keeping within our time limitations.

Mr. Kirk has been the Executive Director of the American Intellectual Property Law Association since 1995—is that correct? He previously held a number of positions at the Patent and Trademark Office, including most recently Deputy Commissioner. He has had extensive experience in patent law in the international context. During his tenure at the Patent and Trademark Office, Mr. Kirk represented the United States in several international treaty obligations, including GATT and WIPO and OECD. And to try to keep some continuity here, he is also a graduate of the Georgetown University Law Center.

What year did you graduate?

Mr. KIRK. I graduated in 1965.

Chairman LEAHY. Mr. Kirk knows why I am grinning. I graduated in 1964.

[Laughter.]

Chairman LEAHY. Go ahead, Mr. Kirk.

STATEMENT OF MICHAEL K. KIRK, EXECUTIVE DIRECTOR, AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, ARLINGTON, VIRGINIA

Mr. KIRK. Thank you, Chairman Leahy, members of the Committee. I am pleased to be here today to offer the views of the

American Intellectual Property Law Association on whether the defenses to infringement in Section 271(g) should be made applicable to Section 337 of the Tariff Act of 1930. I will not go through the details that have already been covered by you, Mr. Chairman, and by Mr. Herrington and Professor Thomas, but let me say that there are significant differences between a Section 337 proceeding in the ITC and an action for patent infringement in a Federal court that make Section 271(g) exceptions inappropriate for Section 337.

The ITC must find that a patentee is actively engaged in exploiting the patent in the United States. The product must have been made by a process covered by a valid and enforceable patent. The remedy is limited to a prospective exclusion order, no monetary damages. The ITC must also consider the public interest, health and welfare, and competitive conditions in the United States before issuing an exclusion order, and the Section 337 determination is subject to Presidential review before becoming final.

In contrast, the district court in a patent infringement action only considers whether the patent is valid, enforceable, and infringed, and both damages and injunctive relief are available.

By adding 271(g) to the patent law, Congress intended to provide additional remedies in Federal court for process patent owners. Congress explicitly stated that it did not intend to undermine any existing remedies available to patent owners in Section 337 proceedings. The Senate report reinforces this point. As we heard from Mr. Herrington, this intent was confirmed by the ITC and the Federal Circuit in *Kinik* v. *International Trade Commission*. We think the Federal Circuit got it right. Congress closed the process patent loophole with passage of 271(g) and was careful not to create a second one. We believe this decision was correct.

The proposed amendment to Section 271(g) would be detrimental to U.S. manufacturers. It would put domestic firms at a competitive disadvantage relative to their foreign competitors. A domestic manufacturer has no defense to a charge of infringing a process patent under Section 271(a) on the ground that the product will later be materially changed or become a trivial and nonessential component of another product.

Its foreign competitors do not face this problem. The practice outside the United States of a process protected by a United States patent is not an infringement of the U.S. patent. There is no Section 271(a) action that can be brought against a foreign company for such activity outside the United States.

If the proposed amendment were adopted, a company in China could transform an intermediate compound—produced according to a patented process—into a chemically different final product and import it with impunity into the United States. Or a company in South Korea might employ a patented method for forming conductive lines on semiconductor wafers as an initial step in manufacturing integrated circuits for use in cell phones that could be imported into the United States, perhaps under either of the two defenses. Protecting American intellectual property against foreign usurpation is already difficult; the amendment would make it more so.

Moreover, the amendment would create a perverse incentive to offshore domestic manufacturing and jobs, as you alluded to, Mr.

Chairman. It could provide an incentive for domestic manufacturers to practice patented manufacturing processes offshore in order to take advantage of the defenses in 271(g), in the same manner as their foreign competitors could, were this amendment to be adopted. Existing pressures already exist to offshore American jobs to take advantage of low labor costs in other countries. Aiding their exodus by weakening protection for U.S. process patents would seem unwise.

For these reasons, AIPLA opposes any amendment to Section 271(g) to create new defenses that would only benefit foreign manufacturers conducting unfair trade practices. Section 337 should not be amended in a manner that would benefit foreign manufacturers at the expense of patent owners, manufacturers, and workers in this country.

Thank you, Mr. Chairman. I would be pleased to answer any questions you might have.

[The prepared statement of Mr. Kirk appears as a submission for the record.]

Chairman LEAHY. Well, thank you very much, Mr. Kirk.

Christopher Cotropia is an associate professor of law at the University of Richmond School of Law, and a member of the school's Intellectual Property Institute. He attended law school at the University of Texas Law School. He clerked for Judge Alvin Schall of the U.S. Court of Appeals for the Federal Circuit. We have two people who clerked for the Court of Appeals for the Federal Circuit. He teaches intellectual property law, patent law, copyright law, cyberlaw, and property.

Please go ahead.

STATEMENT OF CHRISTOPHER A. COTROPIA, PROFESSOR OF LAW, UNIVERSITY OF RICHMOND SCHOOL OF LAW, RICHMOND, VIRGINIA

Mr. COTROPIA. Thank you, Mr. Chairman, and I thank the Committee and the Chairman for the opportunity to testify before the Committee today on the extraterritorial enforcement of a United States process patent. I appear today on my own behalf, as a concerned observer of the patent system.

As has been mentioned before, the issue before the Committee today is very narrow and incredibly complex. I hope to cut through some of this complexity with my testimony today and provide a fair and balanced presentation of the issues that 271(g) exceptions and their inapplicability to the ITC present.

To put it succinctly, there are three issues that are presented by the inapplicability of these exceptions to the ITC: the first is inconsistency of judgments; the second are these international trade issues; and, third, the possible hindrance of the policies behind the exceptions.

One of the other things I would like the Committee to consider is exactly how this issue sits within the context of the broader patent reform that is facing us currently today.

As has been previously mentioned, the *Kinik* decision presents the possibility, although yet not applied, that the exceptions to 271(g) would only apply in district court cases as opposed to cases

before the ITC. I would like to proceed with my testimony just talking about these three issues that I think it presents.

First, inconsistency of judgments. Professor Thomas presents this as one of the potential concerns, the idea being that for the same patent and the same claims someone would not win in the district court proceedings because the exceptions would be applicable. But then at the ITC, with the same patent and the same claims, I could prevail because the exceptions do not apply. This is a potential concern.

There are, however, reasons to not label these judgments as "inconsistent." In some ways, we could be looking at apples and oranges here. If Congress purposely created separate and different types of enforcement mechanisms, then in some ways there is no reason to compare these as equals. This same argument can actually be made at even a higher level. There are different purposes that these two tribunals try to effectuate. United States district courts are tasked with enforcing the patent laws of Title 35, while the ITC is actually tasked with enforcing our trade-related laws and protecting domestic industries.

The second potential concern is the international concerns, and this is more specifically the concern that not allowing these exceptions to apply in the ITC realm would cause us to be in incompliance with TRIPs, particularly Article III of TRIPS, which requires us to not provide someone of foreign origin with less favorable protections than a domestic counterpart. You could see how this could play out. A foreign importer would be subject to in some ways the heightened standards at the ITC, would not be able to avail themselves of those defenses, and, thus, might be found liable at the ITC, while a domestic counterpart in district court would be able to avail themselves of these exceptions. And, thus, we would have a less favorable application to a foreign company.

The problem here with this type of analysis is that we have to look at the totality of the circumstances to determine whether it is less favorable. And as has already been mentioned by Mr. Kirk, there are certain differences between the two jurisdictions, and in some ways district court proceedings can be more onerous because of the monetary relief that is there, and there are some advantages to foreign companies in the ITC. One in particular that was adopted with these amendments is 35 U.S.C. 295, which only applies in district court settings and creates a presumption of infringement in that context, but does not create a presumption of infringement in the ITC context.

The third area of concern is to see whether this might actually hinder the policy concerns behind Section 271(g). In some ways, I think that this is the most important issue, and we really need to consider how much we want to limit the enforcement of process patents outside the United States. To put it another way, how strong do we want process patents to be?

Professor Thomas presents a good argument why this might actually upset the balances in this type of situation, but on the flip side, there could be good arguments to be made that we are just extending the natural protection that you get in the United States to extraterritorial regions. We do not care traditionally under process patents what product was made by the patent or the value the

process presented to that patent. And, thus, we could be simply extending this in the ITC realm to those things that are done abroad.

My final point—and in some ways this is not directly relevant to the 271(g) issue—is that I really think the Committee and Congress should consider this issue in the context of broader patent reform. To get 271(g), the first go-around, it took many years. It also took a bitter battle between industries and much congressional testimony. In some ways, I would like the Committee to take a look at this, an issue that has not actually been applied, and think about it in the broader context, and also think about it being a moving part in the patent reform that has in some ways a higher impact and greater range, that is currently before the Committee and Congress, both the House and the Senate.

Thank you very much, and I look forward to your questions.

[The prepared statement of Mr. Cotropia appears as a submission for the record.]

Chairman LEAHY. Thank you, Professor.

Mr. Herrington, let me refer to Mr. Cotropia's testimony.

Senator GRAHAM. Mr. Chairman, pardon me. I am going to have to leave. Could I submit for the record an article by Mr. Kantor and Mr. Olson reflecting my views? And I apologize to—

Chairman LEAHY. No, it is quite all right. In fact, we will keep the record open for any Senator, we will keep it open for at least 24 hours if any Senator wants to—

Senator GRAHAM. I will take you up on that. This is a very important issue for me in South Carolina, and I appreciate your having this hearing.

Chairman LEAHY. I understand.

Senator GRAHAM. Thank you very much.

Chairman LEAHY. Thank you, and I appreciate your coming here. I know you spent a lot of time on this.

Mr. Herrington, in Professor Cotropia's testimony, he explores whether you apply the 271(g) defenses—if you apply them in the district court but not at the ITC, would that really result in inconsistent decisions? He speaks of the different institutional goals of patent infringement litigation in ITC proceedings. I think I am correctly stating it.

Mr. COTROPIA. That is correct, Chairman.

Chairman LEAHY. Now, can you elaborate, Mr. Herrington, on how the purposes of ITC exclusion proceedings and the remedies available there are distinct from district court patent infringement litigation?

Mr. HERRINGTON. Yes, Mr. Chairman. I can tell you that with respect to the distinctions and similarities, as I mentioned earlier, we adjudicate under the adjudicative provisions of the Administrative Procedure Act. There is an administrative law judge and then potential review by the Commission.

The proceedings before the administrative law judge are very much like a bench trial in a United States district court. There is discovery very similar to the type of discovery that you could get in a district court proceeding. The response times tend to be shorter. The rules of evidence that we apply are the ABA Rules of Evidence, reliable, probative, substantial evidence. We do not directly apply the Federal Rules of Evidence, but we can look to them for

some guidance. There is not a jury, of course. It is just the administrative law judge and ultimately the Commission. We do not award damages.

There are three parties to a Commission 337 proceeding: one is the complainant; one is the respondent, the accused infringer; and the other is the Commission investigative attorney. We have an office at the Commission called the Office of Unfair Import Investigations, and they provide an attorney who acts as a party in every one of our Section 337 investigations at the Commission level, and the purpose of that attorney is to make sure the record is complete and to address public interest concerns.

Of course, our jurisdiction is limited to imports. We do have a domestic industry requirement. Our appeals, appeals from our determinations, are to the Federal Circuit, which is the same court, of course, that hears all appeals from patent cases in district courts.

Chairman LEAHY. Well—oh, go ahead.

Mr. HERRINGTON. I hope I—

Chairman LEAHY. It is such a complex hearing. I may do a followup question on this, but I wanted to go to Professor Thomas for a moment because he had stated several reasons why Congress should change the law so that 271(g) defenses apply in ITC proceedings as well as in patent infringement cases in district court. And the defenses assumed the process used to manufacture the product abroad was a process that, if it was used in the U.S., it would violate a U.S. process patent and, thus, be patent infringement.

The 271(g) defenses simply excuse that action for patent infringement cases where the manufacturing occurred abroad, if the foreign product is sufficiently different than the original product. If you are going to apply the defenses to ITC proceedings, would we not be encouraging companies to produce these products abroad instead of doing them here in the U.S.?

Mr. THOMAS. Well, Mr. Chairman, being just a lawyer and, gee, not only that, just a law professor, these sorts of economic calculations can be difficult to make. But what I would observe—

Chairman LEAHY. I am just a small-town lawyer who lives on a dirt road in Middlesex, Vermont, so I mean, what the heck.

Mr. THOMAS. Well, we will give you credit for your choice of law school, at a minimum, sir.

[Laughter.]

Mr. THOMAS. What I would observe is that simply this situation is complex. For example, when I go to places like South Carolina, I see large Japanese automakers with large plants by the side of Route 95. Many foreign firms have substantial manufacturing in the United States, and many of them, I am sure, want to import component parts for their products that they make in the United States from abroad. Would they cease these activities if they cannot actually import products from abroad because they can be accused of patent infringement in the ITC, but not the district courts?

So it seems to me this account of offshoring in a world with multinationals and distributed manufacturing facilities is a complex one. I am not sure the story is as straightforward that they will simply be saying this is going to promote offshoring.

Chairman LEAHY. Mr. Kirk and Professor Cotropia, do you want to add anything to that?

Mr. KIRK. Chairman Leahy, I come from the perspective that I am not terribly concerned about the difficulties faced by a foreign company, that practices a process that was created and patented in the United States by an American company, which would like to avail itself of the defenses in 271(g) to import that product into the United States. It deprives the patent holder of the revenue it rightly deserves, and it makes a mockery, I believe, of the situation.

The article that Senator Graham asked be put into the record states in part "There is no real harm done to the holder of a process patent if someone produces and imports a significantly different product into the United States. On the other hand, real damage to the economy and to innovation could ensue if these limitations were not built in the law."

I am sorry, sir, but I do not believe a foreign copyist is an innovator. I think they are a copyist, and I do not believe they should be entitled to these defenses.

Chairman LEAHY. I gather that is the way you felt.

Professor Cotropia?

Mr. COTROPIA. The only point I would add to this discussion is that maybe the focus needs to be on the actual incentives of the creation of the process in the first place. In some senses, that is where patent law is trying to target, not a kind of post hoc after the fact taking up of value. So the question becomes whether someone innovating a process needs to have this added protection for its extraterritorial use or not, and clearly Congress thought that it would not be that much harm on the incentive to take that away from them at the district court level.

The question then becomes if we take away that at the ITC level, does that erode too much of the incentive that is there, and I think that is the balancing question that Congress is faced with here.

Chairman LEAHY. Thank you.

Senator Coburn?

Senator COBURN. Just a couple of questions.

It is your opinion, Professor Thomas, that 271(g) right now favors domestic industry.

Mr. THOMAS. It is my opinion that the inapplicability of 271(g) defenses to ITC actions favors domestic industry.

Senator COBURN. And the purpose for favoring the domestic industry was what?

Mr. THOMAS. I believe the purpose speaks for itself. In 1930, the statute was passed to favor domestic industry over foreign competitors.

Senator COBURN. OK. Well, let me go a little further. You all have called in the question of economics and trade and everything else. Tell me, when we look at ITC, where is the legitimacy for a drug manufacturer in this country who may have patent rights in Europe, but then is told what price they will be paid for their drug? If you have intellectual property but yet you have a price control on that otherwise—I guess the thing I am challenging a little bit is how worried we are about our trading partners when, in fact, we are the ones getting the short end of the deal in intellectual prop-

erty throughout the world. That is my view. It may be slanted. It certainly is going on in the Far East and in the Near East, where we lack any capability to enforce our intellectual property.

I hear you and the other professor come and say we should be worried about it. I think there is a cogent argument to be made to say we should not disadvantage somebody under ITC, that we are using two standards. But maybe that is a good standard given the world where it is today rather than taking the presumption that we are worried about trade in the future.

You know, I find that very strange that that figures in to what you all are trying to testify today. We ought to be talking about what are the effects of 271 and what are the effects of the ITC process under it, and let trade fall where it will. If we have true intellectual property, we ought to protect it, and we ought to protect it equally. And trade agreements or not, either that patent means something in this country or it does not.

I know I am not a lawyer, so I am setting this down kind of as a doctor: Where are the symptoms here and where is the disease? The disease is if somebody has a patent on a process and it is their patent, they ought to have adequate protection for that, whether they are trying to do that overseas or they are trying to do it here, especially if they have conquered the patent law overseas.

So help me out. Where does the trade come into this versus the inapplicability of the two sets of performance standards, one under the ITC and one under 271(g)?

Mr. THOMAS. Certainly, sir. First, my sense is that medical pricing bears a tangential relationship to this issue, but I think it is important to remember that the United States is a member of a community of states. We were one of the founding members of the World Trade Organization. As part of that agreement, other member States of the WTO have pledged to dramatically upgrade their intellectual property regimes. When you start speaking about European States, patents on pharmaceuticals are well available there, and there are established enforcement systems, and pharmaceutical companies that are based in the United States quite frequently obtain patents covering processes in those jurisdictions. Those patents remain ready for enforcement at any time by a U.S. firm. In addition—

Senator COBURN. OK. Let me interrupt you just for a second, if I can. Those patents are enforced as long as the pharmaceutical company will agree to sell at the price at which the European country says they are going to pay for it under the threat of "We will allow production of this drug if you do not do that."

Now, tell me in law how that patent is protected when it is, in fact, hung out to dry under the threat of having no patent protection? I mean, that is what we see. Am I incorrect in that? Is that not why we have prices of pharmaceuticals one-half the price they are in this country all across Europe because a fixed price is demanded?

Mr. THOMAS. Well, Mr. Coburn, while I do not claim to have an extraordinary amount of expertise in pharmaceutical pricing under the various laws of Europe, I am not familiar with any regime that denies patent protection to drug companies that do not sell at a particular price. Perhaps they exist. I am certainly not aware of

any European patent law that, in fact, stipulates pricing for particular products as a condition to obtain patent protection.

Senator COBURN. It is not a stated threat. It is an implied threat.

Mr. THOMAS. OK. Well, I am not aware of the express or implied limitations, so your knowledge may exceed my own. I am certainly not aware of it. Certainly many jurisdictions do use an average pricing regime, just as the United States Government uses an average wholesale price for its own Federal employee pricing system.

So I think we cannot point fingers too quickly at prices of medicines that we regulate certainly for Federal employees, and we certainly regulate prices of other products.

I think ultimately, just going back again, we have entered into an international agreement that stipulates, among other things, that our firms can obtain intellectual property rights and enforce them on a nondiscriminatory basis in those countries, and as part of that deal, we have also agreed to apply national treatment and most-favored-nation to our trading partners. And I think as part of that deal, regardless of whether you feel others are scalawags or others are not living up to their bargain, it is important for the United States to set an example and follow the terms of the agreement, in my opinion.

Thank you.

Senator COBURN. Thank you.

Chairman LEAHY. Thank you.

Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman.

I have two questions. The first is how we can make the remedy under the ITC more effective. I appreciate, Mr. Herrington, the work that is done at the Commission, but I know it can take a long time. It can be very expensive, and enforcement through denying entry into the United States is not always effective. So I would be interested in how we could improve the system so that those that violate our intellectual property laws, that the domestic producers have a more effective remedy through the ITC.

Second, Professor Thomas, I think you have sort of provoked my interest. I must confess I do not know the entire history behind the defenses in 271(g), and I am certain they were hard fought and very controversial. But maybe you are convincing me that we should repeal those two exemptions with the district court matters, knowing full well that the dollar amounts that are awarded there would take into consideration what would be included in those defenses anyway.

So why not just, if you are so concerned about our international requirements, consider changing the defenses that are available for those who have violated the patent laws of this country but have the defenses because of the change in status or the minor impact on the product?

Mr. HERRINGTON. Senator Cardin, with respect to the first question you addressed, I had not given that a lot of thought before coming to this hearing. You may know that our caseload has been increasing. It has been increasing very substantially. We are still able to cope with that caseload, and we are taking steps to ensure that we have the appropriate personnel and facilities to make sure that that continues to happen.

I am not sure that I can comment any further on the question.

Senator CARDIN. Well, it may be that some of the procedures or some of the requirements—we found that in some of the ITC areas that I have been involved with on steel and countervailing duties, et cetera, that some of the laws that you operate under make it difficult to comply and some of the court rulings have made it difficult to enforce our laws.

I happen to agree with Senator Coburn. I want to make our intellectual property rights enforceable and I want to make our rules enforceable. So I do not have a lot of sympathy for those who violate them.

Mr. HERRINGTON. Well, we will certainly give that some thought and, mention anything that we think is appropriate.

Senator CARDIN. Thank you.

Professor Thomas, I am looking forward to your reply.

Mr. THOMAS. Mr. Cardin, I hope you have the same sympathy for witnesses before this Committee. Certainly I agree with you to the extent that symmetry of laws between the ITC and district courts—

Senator CARDIN. So you support repealing those?

Mr. THOMAS. Well, I think let me offer a few observations on that point. I am not that familiar with European medical pricing. I am more familiar with European patent laws, and many of them had a provision that essentially inspired 271(g). They called for products that were directly -and I am transliterating, but directly the result of the process.

Senator CARDIN. You are suggesting that we pattern our trade laws after Europe?

Mr. THOMAS. We already have, Mr. Cardin. We—

Senator CARDIN. Certainly that is not true in agriculture.

Mr. THOMAS. Well, the Process Patent Amendments Act certainly was—

Senator CARDIN. Certainly it is not true in the Doha Round where we are getting into all types of problems with Europe.

Mr. THOMAS. All I am suggesting is—in fact, will tell you directly is that the legislative history of the Process Patent Amendments Act accounted for European laws that used words like "directly the product of the process," and I think this was an attempt to articulate a bit further—

Senator CARDIN. So when the European laws favor our foreign competitors, we should use those laws, but not the other ones? I am not—

Mr. THOMAS. Well, if you will allow me to continue, Mr. Cardin, if I may.

Senator CARDIN. Sure.

Mr. THOMAS. One thing to remember is that when the product of the process is subject to a number of modifications or is only tangential to the product, there tends to be some disconnect or at least some separation between the process and the product. And so the notion is perhaps these individuals are not the copyists of which you speak. Perhaps they have done some follow-on innovation themselves to move further.

I would also state that—

Senator CARDIN. Then that wouldn't violate the law. They wouldn't violate the—they would have a defense there.

Mr. THOMAS. Well, they might violate the process patent in the jurisdiction from which that product is exported.

Senator CARDIN. Then they have violated our law.

Mr. THOMAS. Not necessarily under 271(g) in the district courts.

Let me also observe that these situations arise because there is no product patent in the United States. If there is a product patent in the United States, that patent proprietor could enforce the product patent directly. And the reason these cases come up is because there is only a process patent in the United States. And why is there only a process and not a product patent? Usually because patent policy says that there ought not to be, because it is a naturally occurring substance or because the product is already known, and so the only innovation that is done is a new way of making it or using it.

So those policy reasons are well established in the patent law, and they are not by accident. They balance between innovation and access. And so when we say, well, we ought to have expanded protection for sort of a form of patent protection that is regarded as weak, that is sort of at times left to someone who cannot get a full-fledged product patent, we should at least pause, respectfully, I think, before we expand it.

Thank you, Mr. Cardin.

Senator CARDIN. Thank you.

Thank you, Mr. Chairman.

Chairman LEAHY. Senator Cardin, if you have more, feel free.

Senator CARDIN. No, Mr. Chairman. I think I got the answer I expected. I would just come back to the point, if there are additional suggestions that any of the panelists might have, we would certainly appreciate it, because I do think we want our laws enforced.

Thank you.

Chairman LEAHY. In fact, I will keep the record open. There are a couple of points that I would like to explore further. For one thing, take a look at your testimony when you look at it. If you want to add to it, and we will note it as an addition, but we are keeping it open for that. We are not trying to play "gotcha" here. This is too important an issue. It is a highly complex issue, as you know. You have each spent more time on this than most of us have. But it is a very, very worrisome issue.

After I get a chance to read more thoroughly the two cases from yesterday in the Supreme Court, I may followup with some questions based on that. Some of the cases in the Supreme Court—I mean, it is very easy to read a case about chasing a fleeing suspect. The press and everybody else can usually pick up on that, and as a former prosecutor, I read it with interest. But on these, they get a little bit—they do not make for exciting bedtime reading. Perhaps for the four of you they do. They do not for me. But, fortunately, they do for Susan Davies and other brilliant people on the staff. But I may followup based on that, if you do not have any objection.

So we will stand in recess.

[Whereupon, at 3:34 p.m., the Committee was adjourned.]

[Questions and answers and submissions for the record follow.]

QUESTIONS AND ANSWERS

United States Senate
Committee on the Judiciary

Responses to Questions Submitted by Senator Specter, Ranking Member
Re: Hearing on "Process Patents" on May 1, 2007

Christopher A. Cotropia
Associate Professor of Law
University of Richmond School of Law

1. **Upon introduction of the Process Patents Amendment Act in 1988, Senator DeConcini said, "Our laws must enable U.S. companies to protect themselves from foreign manufacturers which steal American owned technology and then use American innovations to compete with U.S. manufactured goods." This statement tends to indicate that the Process Patent Amendments Act was adopted to strengthen the ability of US process patent holders to enforce their U.S process patents. How is this objective served by extending the exceptions to infringement cases at the ITC?**

Response:

This objective can still be served because the technology the Process Patent Amendment Act in 1988 is trying to protect is the patented process, not the products produced by such processes. Traditionally, a process patent holder cannot gain exclusivity over the products made by the patented process. Section 271(g) creates an exception to this notion, using the non-protected, imported products as a vehicle through which U.S. patent holders can enforce their process patents abroad—meeting Senator DeConcini's goal.

The § 271(g) exceptions do not necessarily thwart this goal. The exceptions keep the scope of exclusivity focused on the patented process and, in turn, try to reign in the reach of U.S. process patent holders over products. The exceptions do this by carving out safe harbors in situations were giving the patent holder exclusive control would be closer to giving the process patent holder exclusivity over the product, instead of the patented process. As a result, the § 271(g) exceptions prevent a patent holder from gaining exclusivity over products too far removed from the societal value of the patented process.[1] The § 271(g) exceptions—where the product is "materially changed" or "a trivial and nonessential component of another product"—focus on situations were foreign manufacturers are not truly "steal[ing] American owned technology" nor are they

[1] *See* S. Rep. No. 100-83, at 49-51 (1987) (providing an example of non-infringement where the process is not commercially essential to the creation of the imported product); *Eli Lilly & Co v. Am. Cyanamid Co.*, 82 F.3d 1568, 1572 (Fed. Cir. 1996) (noting Congress's intent in passing the § 271(g) exceptions is to limit protection to actions that impact the commercial value of the patented process).

"us[ing] American innovation to compete with U.S. manufactured goods." In the § 271(g) exception situations, the foreign manufacturers are using U.S. intellectual property (the patented process), but the products that come into the United States derive little to no value from this use.

Thus, applying the § 271(g) exceptions to the ITC would simply extend this rationale to another forum—limiting U.S. process patent enforcement to those situations were the imported products' value is closely tied to the intellectual property right at issue—the process patent.

This question does, however, get at the heart of the issue before the Committee. How strong should process patents be? Do we need to give U.S. process patent holders the ability to capture any and all products made anywhere to maintain the incentive to create the patented process? In some ways, the current situation may strike the best balance. The U.S. process patent holder has the ability to exclude from importation any and all products made by their process via ITC proceedings. But that same patent holder cannot receive monetary damages, or the other benefits, of a district court action under § 271(g). Congress may have, perhaps unintentionally, struck the right balance.

And we have yet to see a clear, detrimental effect on innovation because of the limited application of the §271(g) exceptions. The Federal Circuit has not applied the dicta in *Kinik*, and the § 271(g) exceptions have rarely been applied in district court cases since their 1988 adoption.[2] This all suggests that a wait and see approach may be the best course.

2. Is the U.S. currently in violation of GATT? If not, why not?

Response:

The absence of the § 271(g) exceptions in ITC proceedings is not a violation of GATT. The argument as to why it is a violation would be that by not applying the § 271(g) exceptions at the ITC, a foreign-based importer does not get the same defenses as their domestic counterpart and thus their products are subject to "less favourable" treatment than domestic companies. If this is truly the case, the U.S. would likely violate in violation of Article III of GATT.[3]

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[2] *See* Anne Elise Herold Li, *Is the Federal Circuit Affecting U.S. Treaties? The ITC, § 271(g), GATT/TRIPS & the* Kinik *Decision*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 601, 639-40 (2006) (noting that the exceptions were applied only five times from their adoption until March 28, 2005).

[3] *See* General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194, Article III.

However, to determine whether the treatment is truly "less favourable," the totality of both types of actions must be examined and compared.[4] In the end, since both § 271(g) and the ITC actions stem from importation into the United States, both foreign and domestic companies are effected equally by the lack of § 271(g) exceptions at the ITC. A domestic company can fall within the ITC's jurisdiction because § 1337(a)(1)(B) explicitly covers the "sale within the United States after importation by the owner, importer, or consignee" of infringing products.[5] A domestic company is also indirectly effected by a successful ITC action even if they gain the benefit of the § 271(g) exceptions because any future imports will not be allowed into the country. The domestic company's supply of exempt products under § 271(g) will eventually dry up.

If a domestic company is able to avoid the ITC, a foreign company still gains benefits over its domestic counterpart in district court. The foreign company is not subject to any monetary liability at the ITC. In contrast, if a § 271(g) action is successful, the infringer is, at the very least, liable for reasonable royalties for all past infringements and these damages may be trebled if the infringement is deemed willful.[6] It is also more difficult to prove a foreign company violated § 1337 because the evidentiary presumptions of infringement set forth in 35 U.S.C. § 295 apply only to § 271(g) actions in district court.[7]

This analysis does bring up an important point. The ITC and district court are different forums, with different procedures, and different remedies. But since § 271(g) is essentially concerned with the importation of foreign products, the ITC can dominate both the foreign and national effect of U.S. process patent rights. The Committee should take this into consideration when addressing the base policy question—How strong should process patent rights be?

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[4] This is the same criteria used by a GATT panel when it considered whether the availability of § 1337 action violated Article III of GATT. *See* Report of the Panel, *United States – Section 337 of the Tariff Act of 1930*, L/6439, 38-39 (Nov. 7, 1989).

[5] 19 U.S.C. § 1337(a)(1)(B).

[6] *See* 35 U.S.C. § 284.

[7] *See* 35 U.S.C. § 295 (noting that the presumptions apply "if a court" makes certain findings); *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. Int'l Trade Comm'n*, 224 F.3d 1356, 1360 n.1 (Fed. Cir. 2000) (noting that "it is possible that § 295 has no application to proceedings before the ITC, since the statute on its face applies to courts, not agencies").

3. In relying on the following statement about Congressional intent in a Senate Report on 271(g) --"Neither is there any intention for these provision to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade commission"-- did the Federal Circuit in *Kinik* confuse types of relief available with substantive legal standards as to what constitutes infringement of a US patent?

Response:

It certainly is possible. And this argument has been made by commentators.[8]

However, to the bottom line issue—did the Federal Circuit correctly construe the relevant statutes and limit the application of the § 271(g) exceptions—I believe they did. The most convincing evidence of Congress's intent is that in the same 1988 Act that enacted 35 U.S.C. § 271(g), Congress also deleted 19 U.S.C. § 1337a and repositioned it, with some non-substantive amendments, at 19 U.S.C. § 1337(a)(1)(B)(ii).[9] This created two causes of action before the ITC with respect to patents—one for the importation of articles that "infringe a valid and enforceable United States patent" and another for the importation of articles that "are made . . . by means of[] a process covered by the claims of a valid and enforceable United States patent."[10] Congress, with § 1337(a)(1)(B)(ii), specifically kept a separate cause of action before the ITC that is divorced from the concept of "infringement"—a concept defined by 35 U.S.C. § 271, which includes the §271(g) exceptions. And the self-contained cause of action in § 1337(a)(1)(B)(ii) provides a reach similar to § 271(g) but does not include any exceptions. If Congress truly wanted to have the § 271(g) exceptions apply to all ITC actions, Congress would simply have repealed § 1337a and not moved it into § 1337.[11]

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[8] *See* John M. Eden, *Unnecessary Indeterminacy: Process Patent Protection After* Kinik v. ITC, 2006 DUKE L. & TECH. REV. 9, ¶ 10.

[9] See Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, § 1342, 102 Stat. 1107 (1988); *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1538-40 (Fed. Cir. 1990). Specifically, § 1337(a)(1)(B) now indicates that the following is unlawful:

> The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—
>
> > (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17; or
> > (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

[10] 19 U.S.C. § 1337(a)(1)(B)(i),(ii).

[11] As an aside, if the Committee wants the § 271(g) exceptions to apply to ITC actions, a simple deletion of § 1337(a)(1)(B)(ii) would achieve this result.

United States Senate
Committee on the Judiciary

Responses to Questions Submitted by Senator Whitehouse
Re: Hearing on "Process Patents" on May 1, 2007

Christopher A. Cotropia
Associate Professor of Law
University of Richmond School of Law

1. Do you think it is appropriate for Congress to step in to the middle of a dispute between two parties and change the rules while the litigation is ongoing? While it may not be unprecedented, I think it would be an unwise course. Shouldn't Congress have a "don't intentionally and specifically interfere in litigation" policy?

Response:

Congress should change the law when policy, or the Constitution, dictates that the law should be changed. There are legislative mechanism, such as effective date provisions and grandfather clauses, which can minimize a change's impact on causes of actions already initiated and protect settled expectations.

Congress should also, however, be cautious in basing a legislative change on the impact of one, isolate incident. We have yet to see a clear, detrimental effect on innovation because of the limited application of the §271(g) exceptions. The Federal Circuit has not applied the dicta in *Kinik*, and the § 271(g) exceptions have rarely been applied in district court cases since their 1988 adoption.[1]

Furthermore, this issue needs to be considered in the context of the wider reaching patent reforms currently before both the Senate and the House that address core patent issues.[2] With such larger issues on the table, there is reason to think that Congress should not be distracted by the § 271(g) exceptions issue. Additionally, successful patent reform most likely requires compromise amongst the various constituents. To include another issue such as this one introduces another moving piece that may either upset the current balance in the pending legislation or make it more difficult to reach such a balance. To put it simply, the issue here may be too small, remote, and uncertain to justify Congress's

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[1] *See* Anne Elise Herold Li, *Is the Federal Circuit Affecting U.S. Treaties? The ITC, § 271(g), GATT/TRIPS & the* Kinik *Decision*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 601, 639-40 (2006) (noting that the exceptions were applied only five times from their adoption until March 28, 2005).

[2] *See* Patent Reform Act of 2007, S. 1145, 110th Cong. (2007); Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007).

immediate attention and energy and could possibly negatively impact the likelihood of passage of any broader reaching patent reforms currently before Congress.

2. The ITC and the federal court systems have different purposes and grant different remedies. The ITC exists, in part, to protect American industry and trade – and it provides injunctive relief in the form of exclusion orders; the federal court system, among other things, protects individual rights – and provides relief in the form of damages. Doesn't it make perfect sense that defendants in these different venues can avail themselves of different defenses?

Response:

It certainly does, but care should be given to make sure these differences do not frustrate an overarching substantive policy goal Congress is trying to effectuate.

There is a real possibility that the availability of § 1337 actions at the ITC combined with the absence of the § 271(g) exceptions can dwarf any policy goals behind the availability of exceptions in district court. In both the district court and the ITC cases involving patented process use abroad, the triggering activity is the importation of foreign products. If products that fall under the § 271(g) exceptions can be stopped at the border by the ITC, the availability of such defenses in district court eventually become useless. The U.S. process patent holder can have the ITC exclude the exempted products, and the domestic supply that is protected by the § 271(g) exceptions eventually dries up.

But the U.S. patent holder does not get money damages at the ITC and will have a tougher time proving infringement in the ITC because of the absence of the 35 U.S.C. § 295 presumptions.[3] Depending on how strong of protection Congress wants, this middle of the road situation may strike the right balance. We, quite frankly, do not know if it does, mainly because the *Kinik* decision has yet to be applied and the § 271(g) exceptions are applied so infrequently in district court. This is why Congress may want to wait and see the full effect of limiting the exceptions before acting.

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[3] *See* 35 U.S.C. § 295 (noting that the presumptions apply "if a court" makes certain findings); *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. Int'l Trade Comm'n*, 224 F.3d 1356, 1360 n.1 (Fed. Cir. 2000) (noting that "it is possible that § 295 has no application to proceedings before the ITC, since the statute on its face applies to courts, not agencies").

3. What would be the impact on the American economy, and on American jobs, if we were to expand the number of affirmative defenses available to parties accused of infringing process patents before the ITC? Would it send piracy overseas by expanding the permissible uses of US process patents abroad?

Response:

It is unclear. The real reason it is unclear is that the *Kinik* decision's statement on this issue was dicta and the exclusion of § 271(g) exceptions from the ITC has yet to be fully applied.

One can postulate that currently foreign manufacturers do not infringe U.S. process patents, even if the products would fall under the § 271(g) exceptions, because they know they would be excluded by the ITC. But certainly from the passage of § 271(g) in 1988 to the *Kinik* decision in 2004, more foreign manufacturers would have tried to exploit the § 271(g) exceptions. The fact that they have not either means that everyone subscribed to the *Kinik* decision's statutory interpretation well before the opinion issued or that the § 271(g) exceptions are not ones that a foreign manufacturer can easily take advantage. The former is unlikely. One commentator argues that there are five reasons why the *Kinik* decision's statutory decision is incorrect.[4] Certainly foreign companies would have seen similar arguments and believed the exceptions would apply at the ITC and acted accordingly. This makes the later more likely because the § 271(g) exceptions only exclude enforcement against those activities that gain little to no value from the patent process. The § 271(g) exceptions apply to situations were using the U.S. intellectual property does not gain a foreign manufacturer much. Thus, given the extremely limited historical application of the exceptions, applying them at the ITC may have little effect on U.S. process developers and users.

This is all conjecture, however. Those in industry, that know how the § 271(g) exceptions effect decision making and technological development in the United States and abroad, are better situated to address this question.

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[4] *See* John M. Eden, *Unnecessary Indeterminacy: Process Patent Protection After* Kinik v. ITC, 2006 DUKE L. & TECH. REV. 9, ¶ 10-17.

Questions for the Record
Submitted by Senator Arlen Specter, Ranking Member
Senate Judiciary Committee
"Process Patents"
May 1, 2007

Responses of Wayne Herrington
Assistant General Counsel
U.S. International Trade Commission

Question

1. If a district court applies a legal standard that ultimately absolves a defendant from infringement liability, then why shouldn't this same standard apply in an ITC proceeding where a finding of infringement is a predicate before an exclusionary order is entered?

Response

The Commission acts as a quasi-judicial tribunal in its section 337 investigations according to statutory authority. The Commission applies the patent law (Title 35 of the United States Code) and patent jurisprudence in its patent-based section 337 investigations except in those instances where Congress has stated otherwise. In the *Abrasives* case, the Commission construed the relevant legal provisions and legislative history to indicate the intent of Congress that the defenses of 35 U.S.C. § 271(g)(1) and (2) were not to be applied to proceedings under the Commission's process patent provision, section 337(a)(1)(B)(ii). The Commission reached this conclusion by applying principles of statutory construction, and the U.S. Court of Appeals for the Federal Circuit agreed with the Commission on this point.

Question

2. In exclusion proceedings, what does the ITC consider when determining whether to bar a product from being imported into the U.S.?

Response

In arriving at its determination on whether a product should be excluded from entry into the United States, the Commission first considers whether the complainant has shown that a violation of section 337 exists. In a patent-based case, this means that the complainant must show that the imported articles infringe the asserted patent claims. Where the Commission's process patent provision is involved, the complainant must show that the product is "made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent," as set out in section 337(a)(1)(B)(ii). These showings are subject to applicable defenses, *e.g.*, patent invalidity and unenforceability. The complainant must also show that a domestic industry exists or is in the process of being established, as

required by section 337(a)(2)-(3).

If the foregoing requirements are met, and a violation of section 337 thus established, the Commission ordinarily will issue an exclusion order directing Customs to exclude the infringing articles from entry. There are two types of exclusion orders: a limited exclusion order and a general exclusion order. A limited exclusion order excludes from entry infringing articles from named sources who were respondents in the Commission's investigation. A general exclusion order excludes from entry infringing articles regardless of source, and thus not only applies to persons who were respondents in the Commission's investigation, but also to persons who were not. However, additional criteria (set out in section 337(d)(2)) must be met for issuance of a general exclusion order. In addition to, or in lieu of, an exclusion order, the Commission may issue cease and desist orders against persons who were respondents in the Commission's investigation. Cease and desist orders are usually sought against respondents who have commercially significant domestic inventories.

Notwithstanding a finding of a violation of section 337, the Commission may decline to issue relief after considering the effect of such relief "upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers," as provided, for example, in section 337(d)(1). However, it is rare for the Commission to deny relief on this basis.

The final component of a Commission final determination is the amount of bond importers would have to post to permit importation during the 60-day Presidential review period which follows affirmative Commission determinations, *i.e*, determinations that a violation of section 337 exists and the issuance of remedial orders. During the Presidential review period, the United States Trade Representative, acting under delegated authority from the President, may disapprove the Commission's determination for "policy reasons," as provided in section 337(j). Such disapproval is rare.

Question

3. I understand that during exclusion proceedings, there is an attorney serving the public interest. What public interest does the ITC seek to serve and how is this different from the district courts?

Response

A Commission investigative attorney from the Commission's Office of Unfair Import Investigations is assigned to each of the Commission's section 337 investigations. This office is distinct from the Commission's Office of the General Counsel and does not provide advice to the Commission in individual proceedings. The Commission investigative attorney acts as an independent party in the investigation, representing the public interest by developing relevant information and advocating on behalf of the public an independent position on the issues to

assist the Commission and its Administrative Law Judges in the discharge of their decision-making responsibilities during the course of the investigation. The private parties (the complainant and the respondent) are represented by their own counsel. There is no counterpart to the Commission investigative attorney in district court proceedings.

Question

4. I understand that last year the ITC dismissed without prejudice an exclusion proceeding brought by Amgen against Roche and that an appeal of the dismissal is currently pending before the Federal Circuit. If Congress were to amend 271(g) in the manner discussed today, what impact would that have on future proceedings between these parties before the ITC?

Response

On May 12, 2006, the Commission instituted an investigation under section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337) ("section 337") entitled *Certain Products and Pharmaceutical Compositions Containing Recombinant Human Erythropoietin*, Inv. No. 337-TA-568. The investigation was based on a complaint filed by Amgen Inc. ("Amgen") which asserted infringement of six United States patents. The asserted claims included process claims, product claims, and method of use claims. Amgen named four firms as respondents: Roche Holding Ltd., F. Hoffmann-La Roche, Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively, "Roche"). Since process claims were involved, the investigation was based in part on the Commission's process patent provision, section 337(a)(1)(B)(ii).

On July 7, 2006, the presiding administrative law judge ("ALJ") issued an initial determination ("ID") granting Roche's motion for summary determination (the Commission's equivalent to summary judgment) of no violation of section 337. On August 31, 2006, the Commission determined not to review the ALJ's ID, making it the final determination of the Commission.

Amgen has appealed the Commission's final determination to the U.S. Court of Appeals for the Federal Circuit. The appeal is titled *Amgen Inc. v. International Trade Commission et al.*, Appeal No. 2007-1014. Roche has intervened in the appeal on the side of the Commission. The appeal is fully briefed and awaiting scheduling of oral argument. The issues on appeal are: (1) whether the Commission has jurisdiction over so-called "imminent infringement" in the absence of at least a sale for importation; (2) whether 35 U.S.C. § 271(e)(1) can be raised as a defense in cases involving importations of products made abroad by a patented process, including cases brought under the Commission's process patent provision; and (3) whether the ALJ correctly found that there were no genuine issues of material fact regarding whether the accused importations by Roche fell within the defense of 35 U.S.C. § 271(e)(1).

In the appeal, Amgen has argued that the Federal Circuit's decision in *Kinik Co. v. International Trade Commission* requires that 35 U.S.C. § 271(e)(1) not be available in cases brought under the Commission's process patent provision. In *Kinik*, the Federal Circuit agreed with the

Commission that the defenses of 35 U.S.C. § 271(g)(1) and (2) do not apply to Commission section 337 investigations brought under the Commission's process patent provision. The Commission has argued that *Kinik* is not germane to the question of whether 35 U.S.C. § 271(e)(1) is a defense in section 337 investigations brought under the Commission's process patent provision. The Commission's argument would not be affected by an amendment which would eliminate the language "for purposes of this title" from 35 U.S.C. § 271(g).

The question of how such an amendment might affect the availability of the defenses of 35 U.S.C. § 271(g)(1) and (2) in cases brought under the Commission's process patent provision is another matter. Since the Commission acts as a quasi-judicial tribunal in its section 337 cases, it is not in a position to state what the effect of such an amendment might be in a future case. However, the Commission notes that the language referred to was one of two bases on which the Commission relied in the *Abrasives* case to conclude that the defenses of 35 U.S.C. § 271(g)(1) and (2) were not applicable to section 337 cases brought under the Commission's process patent provision. The other basis for the Commission's decision was section 9006(c) of the Process Patent Amendments Act. The Commission also notes that in considering defenses in cases brought under the Commission's process patent provision, it may be argued that the construction of that provision, section 337(a)(1)(B)(ii), should also be taken into account.

Senator Specter's Questions

1. Can you elaborate on the functions of the International Trade Commission and the district courts with regard to patents?

The International Trade Commission (ITC) and the federal district courts have different functions predicated on different statutory bases. The ITC is an executive branch agency that, *inter alia*, serves the public by determining the effect of imports on U.S. industries and directing actions against certain unfair trade practices. ITC proceedings under Section 337 of the Trade and Tariff Act of 1930, 19 U.S.C. §1337, protect domestic industries and the public interest by empowering the Commission to launch investigations and issue exclusion orders against unfair trade practices. In the case of patented processes practiced abroad, an ITC exclusion order may issue upon a finding of unfair trade practices; if issued, it will be implemented by the United States Customs Service to stop the future importation of goods made offshore by practicing that patented process. By contrast, federal court actions adjudicate civil disputes between private litigants in accordance with the Patent Act, issue temporary and permanent injunctions against future infringement, award damages to redress past infringement, and decide reasonable royalties for future infringement if a permanent injunction is not issued.

There are significant differences between a Section 337 proceeding in the ITC and an action for patent infringement in a federal court. The ITC must find that the patentee is actively engaged in exploiting the patent in the U.S.; the patent must be valid, enforceable, and infringed; the remedy is limited to a prospective exclusion order (no monetary damages are possible); the ITC must consider the public interest, health and welfare, and competitive conditions in the U.S. before issuing an exclusion order; and Section 337 determinations are subject to Presidential review before becoming final. By contrast, a federal district court in a patent infringement action only considers whether the patent is valid, enforceable, and infringed—if so, both damages and injunctive relief are available as remedies. Whereas ITC relief is confined to products at the border, district court infringement actions may target those same products after they have entered U.S. commerce.

2. Throughout the past several months, my staff and I have received information indicating that the Judiciary Committee some years ago was unaware of the impact that changes to the patent law could potentially have on proceedings before the ITC. Given your expertise in this area, are you aware of whether the Committee considered the potential impact the Process Patent Amendments Act would have as evidenced by the legislative history?

It is clear from the language of the Process Patent Amendments Act (PPAA) and its legislative history that Congress intended to add a new federal court remedy for process patent owners, not to subtract from preexisting rights. Not only did Congress consider the impact of the PPAA on pre-existing law, but it explicitly stated that it in no way intended to supplant or undermine any existing rights or remedies available to patent owners in Section 337 proceedings brought in the ITC:

> *"Retention of Other Remedies.—The amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law."*

See subsection (c) of Section 6 of the PPAA.

Mr. Kastenmeier also made it clear that the Committee was quite aware of the differences between ITC and federal court proceedings when, in his remarks introducing the patent reform bills that resulted in the PPAA, he noted that:

> *"Under 19 U.S.C. 1337(a) an aggrieved party can claim that goods are being imported into the United States which have been produced using a process protected by a U.S. patent. While the Tariff Act does provide some protection against this practice the potential remedies are clearly insufficient. ... [S]uch a case turns not on questions of patent law, rather whether the importation is unfair. Finally, and most importantly, the remedy in such an action is insufficient.*

Cong. Rec., 11/18/83, p. E5700.

The legislative history on this point is equally clear. The Senate Report states:

> *"The new remedies for process patent owners provided by the bill are subject to general limitations which do not apply in suits under existing law by process patent owners against parties manufacturing in the United States. For example, . . . [t]he bill provides that a product which is made by a patented process will not be considered so made after it is materially changed by subsequent processes; or it becomes a trivial and nonessential component of another product. <u>There is no intention to impose any of these limitations on owners of product patents or on owners of process patents in suits they are able to bring under existing law. Neither is there any intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission."</u>*

S. Rep. No. 100-83 at 60-61 (1987) (emphasis added).

3. Does the Kinik decision undermine the preclusive effect that federal court rulings are traditionally given in subsequent ITC proceedings?

Consistent with the language of the statute and its legislative history, in *Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359 (Fed. Cir. 2004) the Federal Circuit affirmed that the PPAA did not create new defenses for respondents in Section 337 proceedings brought in the ITC. Specifically, the Federal Circuit affirmed the ITC's holding that the two affirmative defenses to infringement under Section 271(g) – exempting a product made by a patented process if that product is "materially changed by subsequent processes" or "becomes a trivial and nonessential component of another product" – do not apply in Section 337 proceedings before the ITC.

The Kinik decision in no way alters any preclusive effect of federal court rulings in subsequent ITC proceedings; it merely confirms that the two special defenses to patent infringement available under Section 271(g) in federal court are not available as defenses to unfair trade practices at the ITC. If a federal court finds that a product is made abroad by a patented process, it might also conclude that the product "will, for purposes of this title, not be considered to be so made" after applying the special 271(g) defenses. In that case, the ITC can rely on the district court's factual finding without observing the fiction to the contrary created by those inapt defenses. It can thereby conclude that there is an unfair trade practice and issue an appropriate exclusion order if the other predicates to such an order are present.

4. How do you respond to Mr. Thomas' statement that, "like cases should be decided alike, regardless of the forum in which the case was heard"?

There is no need to test Mr. Thomas' thesis in this instance, because here the cases are not alike when properly considered. There are significant differences between a Section 337 unfair trade proceeding in the ITC and a Section 271(g) action for patent infringement in federal court.

Section 337 proceedings include, as a participant, the agency that is charged with considering the effect on domestic industry and the public interest in protecting against the importation of goods made offshore by a foreign party using a process protected by a U.S. patent. The Commission determines whether to institute an investigation, participates in the discovery process, motion practice and other pre-trial proceedings, presents evidence and argument at trial, and briefs and argues post-trial motions and any appeal. To prevail in a Section 337 action, the patent owner must show not only use of a process covered by a valid, enforceable claim of a patent, but also that it has created a domestic industry that would be harmed by the importation

and that the public interest would be served by the issuance of an exclusion order.

In contrast, federal courts adjudicate disputes between private litigants, reviewing evidence of patent validity, enforceability, and infringement, and awarding damages to redress past infringement and reasonable royalties for future infringement if a permanent injunction is not issued. Because the parties, the interests in contention, and the available remedies are different, Mr. Thomas' underlying thesis is inapposite. There is nothing inconsistent with Congress's decision, in passing the PPAA, not to extend the two specific defenses to patent infringement under Section 271(g) to the pre-existing trade related law regarding Section 337 proceedings in the ITC.

Senator Whitehouse's Questions

1. Do you think it is appropriate for Congress to step in to the middle of a dispute between two parties and change the rules while the litigation is ongoing? While it may not be unprecedented, I think it would be an unwise course. Shouldn't Congress have a "don't intentionally and specifically interfere in litigation" policy?

No, it is not appropriate. I believe it is unwise and unfair for Congress to intervene in a pending litigation and "change the rules" in the course of an ongoing legal dispute. Parties evaluate their respective legal positions and engage in litigation under the law as they understand and interpret it at a given time, and Congress should strive not to take any action that would upset the balance between the parties as it existed at the outset. To the extent that Congress finds it appropriate to change or clarify existing law, it should normally be done in a prospective manner, permitting the modifications to become effective at some future date certain. Regarding the instant question of modifying Section 271(g) of the Patent Statute, the proposed changes are not needed and would be detrimental to the U.S. economy.

2. The ITC and the federal court systems have different purposes and grant different remedies. The ITC exists, in part, to protect American industry and trade – and it provides injunctive relief in the form of exclusion orders; the federal court system, among other things, protects individual rights – and provides relief in the form of damages. Doesn't it make perfect sense that defendants in these different venues can avail themselves of different defenses?

Yes, it makes perfect sense that infringement defendants in private litigation in federal court have access to the defenses provided to them by Congress, while defendants before the ITC that threaten American industry and trade not be allowed to assert these defenses. That is precisely why the restrictive language "for purposes of this title" was included in Section 271(g).

Congress enacted the Process Patents Amendment Act (PPAA) after years of debate and numerous compromises. The PPAA was intended, in part, to place domestic manufacturers on a more level playing field with foreign manufacturers. It accomplishes this by giving the owners of U.S. process patents the ability to seek injunctive relief and damages in federal court against infringers who are evading U.S. process patents by practicing overseas some or all of a process patented in the United States and then importing the resulting product for sale in the United States. Because the parties, the interests in contention, and the available remedies before the ITC and in federal court are different, it is perfectly logical, consistent and

appropriate for Congress to have declined to extend the newly created Section 271(g) defenses to the pre-existing process under ITC Section 337.

3. What would be the impact on the American economy, and on American jobs, if we were to expand the number of affirmative defenses available to parties accused of infringing process patents before the ITC? Would it send piracy overseas by expanding the permissible uses of US process patents abroad?

An inevitable result of making the Section 271(g) defenses available in ITC proceedings would be that processes invented and patented in the U.S. would be used offshore to produce products for sale in the U.S. If foreign manufacturers were provided with these additional defenses in Section 337 proceedings, with the consequent lessening of the ability of the ITC to exclude such products at the U.S. border, products now made in the U.S. by American workers would instead be made offshore using lower cost foreign labor. The projected result would be the export of American jobs and an increase in the trade deficit.

Section 337 proceedings in the ITC have long been an effective means of protecting domestic industry against the importation of products made by infringing processes practiced abroad. The addition of Section 271(g) to the Patent Act was intended to strengthen the rights of process patent owners, not to weaken the ability of the ITC to protect the U.S. economy. Expanding the defenses available in ITC proceedings would put United States industry at a disadvantage with respect to foreign competitors, by increasing the ability of foreign manufacturers to practice United States process patents abroad and then import the products made by the patented process for sale in the United States. This would encourage off-shoring by creating a perverse incentive to export manufacturing processes and jobs to foreign countries, where the rights of U.S. process patent owners could be ignored, directly contrary to the purpose of the PPAA and undercutting the longstanding right of U.S. process patent owners to seek the ITC's assistance in protecting established domestic industries.

GEORGETOWN UNIVERSITY LAW CENTER

May 29, 2007

The Honorable Patrick J. Leahy
United States Senate
Committee on the Judiciary
Washington, DC 20510-6275

Dear Senator Leahy:

Thank you for the opportunity to reply to the additional questions posed by your colleagues on the United States Senate Committee on the Judiciary. I submit these responses on my own behalf. These views are not necessarily those of any other individual, enterprise, or organization.

Questions from Senator Specter

1. If we change the law to make the 271(g) defenses apply in the ITC, wouldn't that create an incentive for manufacturers abroad to infringe US process patents in other countries for subsequent importation to the U.S.?

Absent empirical evidence on this issue, I simply do not stand in a position to be able to respond to this question in a responsible way. I observe, however, that this amendment could just as readily be seen as encouraging manufacturing in the United States. Both U.S. and foreign firms manufacture complex products in the United States, and they not infrequently import various components of those products from abroad. If U.S. process patents regulate the importation of those components–even where the relationship between the patent and the component is tangential–then the failure to apply the § 271(g) defenses in ITC actions may discourage firms from domestic manufacture altogether.

I also hasten to note that the issue addressed in the hearing of May 1, 2007, was not the proposed elimination of the rule that importation of the product of a process patented in the United States will ordinarily infringe the U.S. patent. Rather, the issue was the extent of a U.S. process patent's extraterritorial interest, and in particular whether products that bear only a tangential relationship to a patented process should still fall within the exclusionary scope of that patent. The incentive that this question suggests is, at most, the incentive to practice a patented process overseas, but then either (1) materially change the product of that process, or (2) ensure that the product of that process becomes a trivial and nonessential component of another product, prior to importing that product into the United States. When it enacted § 271(g), Congress made the judgment that a cause of action for patent infringement in the United States was not justified in these remote circumstances.

The current disconnect between the Patent and Tariff Acts causes the federal administrative and judicial apparatus to continue to react to these scenarios, in contradiction to congressional intent in enacting the Process Patents Amendment Act.

2. Mr. Thomas, is there an actual problem that is in need of Congressional attention or only the potential for a problem? The Federal Circuit has yet to apply the dicta of Kinik *and with so many other issues being presented to Congress in the patent reform debate, is there a reason why Congress should amend this portion of the patent code when it is clear that there is still a substantial question as to whether it is necessary?*

Indications exist that the disharmony in process patent enforcement may constitute a current problem, rather than merely a potential one. Scholarly commentary has opined that the disjunction between the Patent Act and the Tariff Act violates commitments made by the United States when joining the World Trade Organization. Providing domestic industry with more favorable substantive patent law rules also conflicts with longstanding U.S. policy to improve intellectual property protection available to domestic innovators in foreign markets. The number of products–including medications and other health-related products–that have been denied to U.S. consumers, based upon their tangential relationship to a U.S. process patent, is also unknowable.

It should be also be appreciated that Congress has historically intervened in patent matters on an irregular basis. The last major overhaul of the patent code took place in 1952. Current discussion concerning omnibus patent reform may provide members of Congress, and their staff, with a level of sophistication concerning the patent system that may not be easily reconstructed in the future. As a result, current patent reform initiatives may provide a moment of opportunity for consideration of this fairly technical issue within the patent and trade laws.

Questions from Senator Whitehouse

1. Do you think it is appropriate for Congress to step into the middle of a dispute between two parties and change the rules while the litigation is ongoing? While it may not be unprecedented, I think it would be an unwise course. Shouldn't Congress have a "don't intentionally and specifically interfere in litigation" policy?

I am aware that there is an ongoing dispute between Amgen and Roche that implicates the applicability of § 271(g) issues before the ITC; that statement is essentially the extent of my knowledge as to that disagreement. It should be appreciated, however, that the current disharmony in U.S. process patent enforcement may transcend a particular litigation between two commercial rivals. Academic commentary suggests that this disjunction constitutes a continuing violation of commitments made by the United States when joining the World Trade Organization. We also have no reliable way of knowing the number of products that firms opt not to introduce into the U.S. marketplace due to concerns over process patent infringement–despite the tangential relationship between the U.S. patent

and the product that would ultimately be introduced into the United States. The expansion of the proprietary extraterritorial rights associated with U.S. process patents, in contradiction to congressional intent in framing the Process Patents Amendment Act, may result in higher prices and diminished supplies for U.S. consumers in such crucial areas as pharmaceuticals and other medical products. For these reasons, Congress may properly judge this issue to be one that encompasses policy concerns that extend beyond a particular lawsuit.

2. The ITC and the federal court systems have different purposes and grant different remedies. The ITC exists, in part, to protect American industry and trade–and it provides injunctive relief in the form of exclusion orders; the federal court system, among other things, protects individual rights–and provides relief in the form of damages. Doesn't it make sense that defendants in these different venues can avail themselves of different defenses?

It is true that the ITC and the federal courts have different purposes. Of course it is also true that the remedies vary between the two fora, in that the relief available from the ITC is essentially a subset of that available from the federal courts. These premises do not logically result in the conclusion that substantive patent law rules should vary between the ITC and the federal courts, however. The legal and economic instrument that the moving party invokes in both fora is the same: An issued U.S. patent. Whether the ultimate purpose of enforcing that patent is styled as protecting U.S. industry, or as vindicating the right of an individual participant within U.S. industry, compelling policy reasons indicate that substantive legal rights should not vary among different fora. Holding otherwise violates a fundamental axiom of a just system of laws, the intuitive norm that like cases should be resolved alike. It also leads to other deleterious consequences, including bypassing the balance that Congress achieved in enacting the Process Patents Amendments Act, as well as undermining the preclusive effect that ITC rulings ordinarily enjoy before the federal courts.

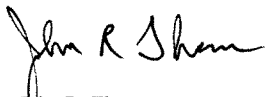
3. What would be the impact on the American economy, and on American jobs, if we were to expand on the number of affirmative defenses available to parties accused of infringing process patents before the ITC? Would it send piracy overseas by expanding the permissible uses of US process patents abroad?

Once again, absent empirical evidence on this issue, I simply do not stand in a position to be able to respond to this question in a responsible way. In a world where multinational enterprises increasingly operate distributed manufacturing facilities, however, the account that ecumenical application of the § 271(g) defenses would encourage offshoring or overseas patent infringement strikes me as at best incomplete. For example, both U.S. and foreign firms manufacture complex products in the United States, and they not infrequently import various components of those products from abroad. If U.S. process patents regulate the importation of those components–even where the relationship between the patent and the component is tangential–then the failure to apply the § 271(g) defenses in ITC actions may discourage firms from manufacturing in the United States in the first place.

* * *

Thank you again for the opportunity to respond to these questions. If I may be of any further assistance, please do not hesitate to contact me at 202 662-9925, or at jrt6@law.georgetown.edu.

Sincerely yours,



John R. Thomas
Professor of Law

SUBMISSIONS FOR THE RECORD

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LEGISLATIVE ALERT!

(202) 637-5090

February 21, 2007

The Honorable Patrick J. Leahy, Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington D.C. 20510

The Honorable Arlen Specter, Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Leahy and Ranking Member Specter:

I am writing to express the AFL-CIO's strong opposition to proposals to weaken U.S. patent law in ways that would effectively encourage offshore outsourcing of U.S. manufacturing jobs. Protecting innovation and ensuring that domestic producers do not face unfair competition from offshore production is critical to creating and retaining good jobs here in the United States. With the U.S. trade deficit hitting record highs and good jobs being lost in both manufacturing and services, it is especially important that Congress retain strong and effective patent protections for U.S.-based producers.

We understand that efforts are being made to amend 35 U.S.C 271(g), a provision of the patent code, by striking the words, "for purposes of this title." This apparently minor change would weaken U.S. process patent protection because it would allow producers outside the U.S. to use patented processes and import and sell the resulting products without respecting the innovators' patent rights. This would have the effect of treating foreign producers more leniently than we treat domestic manufacturers who infringe process patents, enhancing incentives to move production offshore and thereby exacerbating our trade imbalance.

Currently, the U.S. International Trade Commission (ITC) is charged with protecting American workers and businesses from unfair competition. The proposed change to 271(g) seeks to undermine the ITC's ability to prevent foreign products that violate U.S. process patents from entering the country.

This proposed change to the patent code is contrary to the interests of American workers and producers. We ask you to oppose efforts to include this change to 271(g) in the introduced version of the patent reform bill or in any other vehicle. Proponents attempted to attach this modification of 271(g) in a patent rider on the Senate's CJS appropriations bill in the last Congress and have still not given up trying to weaken the ITC's ability to enforce fair trade laws.

Like many in the university community and the private sector, we firmly support current law, which enables the ITC to protect against unfair trade. We strongly oppose any changes to patent or trade law that would allow foreign competitors to infringe U.S. process patents in ways that domestic producers cannot.

Sincerely,

William Samuel, Director
DEPARTMENT OF LEGISLATION

United States Senate
Committee on the Judiciary

Hearing on "Process Patents"
May 1, 2007

Written Statement of Christopher A. Cotropia*
Associate Professor of Law
University of Richmond School of Law

Thank you for the opportunity to testify before the Committee on the extraterritorial enforcement of United States process patents. I appear today on my own behalf, as a concerned observer of the patent system.

The issue before the Committee is very narrow and incredibly complex. This issue focuses on United States patents that cover a process, the unauthorized use of these patented processes outside this country to make products, the importation of these products into this country, and the exception of some of these products from liability. This issue also involves the institutional differences between patent actions in United States District Courts and at the International Trade Commission ("ITC").

This statement hopes to cut through some of the complexity and provide a fair and balanced presentation of the various concerns this issue presents. To put it succinctly, the potential inapplicability of the 35 U.S.C. § 271(g) exceptions to proceedings at the ITC raises three concerns: inconsistent judgments; noncompliance with TRIPs; and hindrance of the policies behind the exceptions. This statement concludes by urging the Committee to consider whether addressing this issue is a road worth going down when Congress is already focused on broader reaching, and higher impact, patent reforms.

Background on the Extraterritorial Enforcement of Process Patents

Prior to the passage of 35 U.S.C. § 271(g), the holder of a United States process patent could exclude only uses of the patented process within the United States.[1] The owner's only recourse to usage of the patented process outside this country was to go before the ITC and seek

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* Christopher Cotropia is an Associate Professor of Law at the University of Richmond School of Law. He is also a member of the School's Intellectual Property Institute. He teaches intellectual property, patent law, copyright law, computer law, and property. He has authored numerous articles in the areas of patent law and federal courts. Professor Cotropia received his B.S. in both Electrical Engineering and Computer Engineering from Northwestern University. He received his J.D. from The University of Texas School of Law, where he graduated Order of the Coif and served as an editor of the Texas Intellectual Property Law Journal. He then clerked for the Honorable Alvin A. Schall of the United States Court of Appeals for the Federal Circuit.

[1] 35 U.S.C. § 271(a).

to exclude from importation products made abroad by the patent process.[2] The patent owner had no recourse in federal district court.

Section 271(g) was enacted in 1988 to close this loophole and provide a cause of action in district court.[3] Specifically, the statute provides that "[w]hoever without authority imports into the United States, or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer."[4] A patent holder can now seek redress both in district court and before the ITC for extraterritorial use of her patented process. Products made abroad by a process patented in the United States can either be the subject of an injunction issued by a United States District Court or excluded at the border by Customs as the result of an ITC issued exclusionary order.[5] The patent holder can also seek monetary damages for harm already caused by this infringing activity, but this relief is only available in federal district court.[6]

When passing § 271(g), Congress noted that other countries limited the scope of exclusivity to products made "directly" from the patented process.[7] While not adopting the "directly" language,[8] Congress added the two exceptions to § 271(g)'s, excluding a product from infringement if "(1) it is materially changed by subsequent processes; or (2) it becomes a trivial

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[2] 19 U.S.C. § 1337a (1982). Section 1337a, enacted in 1940, read as follows:

> The importation for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered by the claims of any unexpired valid United States Letters Patent, shall have the same status for the purposes of section 1337 of this title as the importation of any product or article covered by the claims of any unexpired valid United States Letters Patent.

Act July 2, 1940, c. 515, 54 Stat. 724. The statute has since been repealed and the language placed in 19 U.S.C. § 1337(a)(1)(B)(ii).

[3] *See* Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, § 9003, 102 Stat. 1107, 1563-65 (1988); Anne Elise Herold Li, *Is the Federal Circuit Affecting U.S. Treaties? The ITC, § 271(g), GATT/TRIPS & the* Kinik *Decision*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 601, 608 (2006). Section 271(g) was part of a subsection of the Act subtitled "The Process Patent Amendments Act of 1988".

[4] 35 U.S.C. § 271(g).

[5] 35 U.S.C. § 283 (noting a district court's discretion to issue an injunction); 19 U.S.C. § 1337(e) (identifying the ITC's ability to exclude infringing articles).

[6] 35 U.S.C. § 285. There is a limitation to such damages unique to § 271(g) actions. *See* 35 U.S.C. § 287 (limiting the scope of damages based on notice, as well as other factors).

[7] S. Rep. No. 100-83, at 31-35, 49-50 (1987).

[8] *Id.* at 49 (noting that "directly" was not used so as to not "exempt too many products" from infringement).

and nonessential component of another product."[9] These exceptions were included to ensure that infringing products had "a reasonable nexus with the patented process."[10]

In the same 1988 Act that enacted 35 U.S.C. § 271(g), Congress also deleted 19 U.S.C. § 1337a and repositioned it, with some non-substantive amendments, at 19 U.S.C. § 1337(a)(1)(B)(ii).[11] Essentially there are two causes of action before the ITC with respect to patents—one for the importation of articles that "infringe a valid and enforceable United States patent" and another for the importation of articles that "are made . . . by means of[] a process covered by the claims of a valid and enforceable United States patent."[12]

The *Kinik* Decision

In *Kinik Co. v. International Trade Commission*, the Federal Circuit addressed whether the exceptions in § 271(g) were available to a respondent in an ITC action under § 1337.[13] The patent at issue claimed a process for producing certain abrasive articles, and Kinik was allegedly importing products made by this patented process in Taiwan.[14] 3M, the owner of the process patent at issue, initiated an action under § 1337(a)(1)(B)(ii) before the ITC to exclude Kinik from importing these products.[15] Kinik alleged, among other things, that the imported products were "materially changed by subsequent processes," falling within the exception in § 271(g)(1) and thus could not be subject to exclusion. The ITC dismissed Kinik's argument as contrary to the plain meaning of the relevant statutes and the respective legislative history.

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[9] 35 U.S.C. § 271(g).

[10] S. Rep. No. 100-83, at 36.

[11] See Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, § 1342, 102 Stat. 1107 (1988); *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1538-40 (Fed. Cir. 1990). Specifically, § 1337(a)(1)(B) now indicates that the following is unlawful:

> The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—
>
> > (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17; or
> > (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

[12] 19 U.S.C. § 1337(a)(1)(B)(i),(ii).

[13] 362 F.3d 1359, 1361 (Fed. Cir. 2004).

[14] *Id.*

[15] *Id.*

The Federal Circuit agreed, concluding that the § 271(g) exceptions did not apply to § 1337(a)(1)(B)(ii) actions.[16] The court noted that § 9006(c) of the Act enacting § 271(g) explicitly indicated that there "amendments . . . shall not deprive a patent holder of any remedies available . . . under section 337 of the Tariff Act of 1930."[17] The Senate Report supported this statement, indicating:

> There is no intention to impose any of these limitations on owners of products or on owners of process patents in suits they are able to bring under existing law. Neither is there any intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.[18]

The language of § 271(g) also specifically prefaced the exceptions as being "for the purpose of this title," and thus not applying to Title 19 and specifically 19 U.S.C. § 1337.[19] The court also concluded that it was willing to defer to the ITC's statutory interpretation on this issue.[20]

Notably, the Federal Circuit found the process patent not infringed by Kinik, rendering moot the court's discussion as to whether the exceptions applied.[21]

Potential Concerns Raised by the Inapplicability of the § 271(g) Exceptions at the ITC

The *Kinik* decision, while yet to be applied, identifies the possibility that, as drafted, the exceptions in § 271(g) may apply only in district court proceedings and not in § 1337 actions before the ITC. The rest this statement does not focus on whether the Federal Circuit in *Kinik* was right as a matter of statutory construction.[22] Instead, this statement assumes courts will follow *Kinik* and focuses on the various issues Congress should consider were it to make amendments to introduce the § 271(g) exclusions into ITC actions. There are three areas of concern Congress should take into account.

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[16] *Id.* at 1362-63.

[17] *Id.* at 1362 (quoting Pub. L. 100-418, § 9006(c)).

[18] *Kinik*, 362 F.3d at 1362-63 (quoting S.Rep. No. 100-83 at 60-61).

[19] *Kinik*, 362 F.3d at 1363 (quoting 35 U.S.C. § 271(g)).

[20] *Kinik*, 362 F.3d at 1363.

[21] *Id.* at 1366; *see also* John M. Eden, *Unnecessary Indeterminacy: Process Patent Protection After* Kinik v. ITC, 2006 DUKE L. & TECH. REV. 9, ¶ 2 (noting that the Federal Circuit's interpretation of the § 271(g) exceptions is dicta).

[22] Some have argued that this statutory construction is wrong. Eden, *supra* note 20, at ¶10-17 (identifying five reasons why the court's interpretation is incorrect).

1. Inconsistent Judgments

First, there is a potential for inconsistent judgments on the same patent claims for the same imported products.[23] For example, a company may import a product that, while made abroad by a process patented in the United States, has been materially changed by subsequent processes. This product would fall within the § 271(g)(1) exception, and the process patent holder could not succeed in a district court action of infringement. However, that same patent holder could succeed in an ITC action concerning the very same product because the presence of a subsequent material change is statutorily irrelevant. And neither of these judgments would preclude the other because the § 271(g) exceptions were only legally available in one forum—district court.[24]

There are, however, reasons not to label these as truly "inconsistent" judgments. That is, we may be comparing apples and oranges. Initially, if Congress purposively created separate and different standards for the two causes of actions, there is no reason to compare them as equals. There is legislative history regarding § 271(g) to support this interpretation.[25] This same argument can be made at even a higher level, focusing on the very different purposes of the two tribunals. District courts pursuant to Title 35 are tasked with the specific mandate to enforce patent protections, while the ITC under Title 19 is meant to police trade-related activities and protect domestic industries.[26] These different institutional goals are also exemplified by the fact that "Congress did not intend decisions of the ITC on patent issues to have preclusive effect" on district court proceedings.[27] There is even evidence in the legislative history that Congress recognized, and relied on, these very institutional differences when passing § 271(g).[28]

In addition, because of the lack of a claim preclusion effect for ITC decisions, the possibility of judgment inconsistency is an inherent characteristic of every § 1337 actions. Even

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[23] *See* Li, *supra* note 3, at 639 (identifying this possibility).

[24] *See Brown v. Felsen*, 442 U.S. 127, 131 (1979) ("Res judicata prevents litigation of all grounds for, or defenses to, recovery that were previously available to the parties, regardless of whether they were asserted or determined in the prior proceeding.")

[25] *See, e.g.*, S. Rep. No. 100-83, at 60-61 ("There is no intention to impose any of these limitations on owners of products or on owners of process patents in suits they are able to bring under existing law. Neither is there any intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.").

[26] *See, e.g.*, 19 U.S.C. § 1337(a)(2),(3); *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1019, (Fed. Cir. 1987) (noting that "the Senate Report accompanying the Trade Act of 1974 made clear that the Commission's primary responsibility is to administer the trade laws, not the patent laws").

[27] *See Tandon*, 831 F.2d at 1019.

[28] *See, e.g.*, S. Rep. No. 100-83, at 36-39 (citing an example were a company may be able to successfully enforce their process patent in district court under § 271(g), but not at the ITC because the patent holder has yet to establish a domestic industry).

if there is no difference in substantive law, district courts can, and do, come to opposite conclusions from the ITC.[29] And partially because of this ever-present chance of inconsistency, there are safety valves in § 1337's remedial structure that can rectify such inconsistencies. For example, the ITC is instructed to consider the "public health and welfare" and "competitive conditions in the United States economy" before excluding products from entry.[30] ITC decisions are also subject to presidential review before any remedy goes into effect, explicitly giving the President ability to disapprove of the decision "for policy reasons."[31]

2. Noncompliance with TRIPs

Second, the possibility of inconsistent treatment of like cases presents international concerns. Article III of the Agreement of Trade-Related Aspects of Intellectual Property Rights ("TRIPs") requires each member to "accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property . . . ."[32] By not applying the § 271(g) exceptions at the ITC, a foreign-based importer does not get the same defenses as their domestic counterpart. A foreign company importing products into the United States who has no domestic presence is only directly affected by an ITC exclusionary order. In contrast, a domestic distributor is usually outside the jurisdiction of the ITC and subject only to a district court infringement action.[33] If both are moving products made abroad by a United States patented process, the foreign company will not get the benefit of the exceptions in § 271(g), while the domestic company will. Since the foreign company is subject to a more stringent exclusion of products made by a patented process, they can be said to be subject to "less favourable" treatment than domestic companies.[34]

However, to determine whether the treatment is truly "less favourable," the full effect of both types of actions must be examined. While a foreign company does not get the benefit of the § 271(g) exceptions at the ITC, it does gain other benefits over its domestic counterpart in district court. The foreign company is not subject to any monetary liability. In contrast, if a § 271(g) action is successful, the infringer is, at the very least, liable for reasonable royalties for all past infringements and these damages may be trebled if the infringement is deemed willful.[35]

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[29] *See* Tex. Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1569 (Fed. Cir. 1996) (affirming a district court judgment of non-infringement, even though the ITC found the patents infringed).

[30] 19 U.S.C. § 1337(d)(1).

[31] 19 U.S.C. § 1337(j)(2); *But see*, Li, *supra* note 3, at 645 (noting that the presidential review period will likely pass before the district court makes a substantive decision).

[32] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 3, Apr. 15, 1994, Marakesh Agreement Establishing the WTO, Annex 1C, Legal Instruments--Results of the Uruguay Round vol. 31, 33 I.L.M. 81.

[33] The ITC does have limited jurisdiction over sales by importers, owners, and consignees in the United States. *See* 19 U.S.C. § 1337(a)(1)(B).

[34] *See* Li, *supra* note 3, at 635-36 (making a similar argument).

[35] *See* 35 U.S.C. § 284.

A patent holder will also find it more difficult to prove a foreign company violated § 1337 because the evidentiary presumptions of infringement set forth in 35 U.S.C. § 295 apply only to § 271(g) actions in district court.[36] Additionally, the domestic company can still fall within the ITC's jurisdiction because § 1337(a)(1)(B) explicitly covers the "sale within the United States after importation by the owner, importer, or consignee" of infringing products.[37] Finally, a domestic company will be indirectly effected by a successful ITC action even if they gain the benefit of the § 271(g) exceptions because any future imports will not be allowed into the country. The domestic company's supply of exempt products under § 271(g) will eventually dry up.

3. Hindrance of the Policies Behind the § 271(g) Exceptions

Third, Congress should consider the policy reasons behind the § 271(g) exceptions. Section 271(g) was enacted to strengthen the protection for United States process patents. In turn, § 271(g) is meant to preserve the incentive to invest research and development dollars in the development of publicly beneficial processes.[38] The exceptions evidence a congressional intent to not overincentivize and provide a patent holder with exclusivity over products too far removed from the societal value of the patented process.[39] Additionally, the exceptions strike a balance between protecting a patent holder's rights and recognizing the territorial limits of United States patents. Finally, the exceptions properly limit culpability to those with products closely tied to the patented process since it is the process, not the product, that is truly infringing. Allowing the patent holder to go to the ITC and exclude products that fall within these exceptions hinders these policies.

However, it can be argued that limiting the exceptions to district courts furthers patent policy. Patent law traditionally gives the patent holder the ability to exclude the use of a patented process to make any product, regardless of how valuable the process is to the made product. Section 1337 operates as intended and simply extends this policy to uses of the patented process outside the United States.[40] The § 271(g) exceptions still place limitations on

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[36] *See* 35 U.S.C. § 295 (noting that the presumptions apply "if a court" makes certain findings); *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. Int'l Trade Comm'n*, 224 F.3d 1356, 1360 n.1 (Fed. Cir. 2000) (noting that "it is possible that § 295 has no application to proceedings before the ITC, since the statute on its face applies to courts, not agencies").

[37] 19 U.S.C. § 1337(a)(1)(B).

[38] *See* S. Rep. No. 100-83, at 30-31.

[39] *See id.*, at 49-51 (providing an example of non-infringement where the process is not commercially essential to the creation of the imported product); *Eli Lilly & Co v. Am. Cyanamid Co.*, 82 F.3d 1568, 1572 (Fed. Cir. 1996) (noting Congress's intent in passing the § 271(g) exceptions is to limit protection to actions that impact the commercial value of the patented process).

[40] *See, e.g., Amgen*, 902 F.3d at 1539 (citing the testimony of Senator Lautenberg regarding the moving of § 1337a to 19 U.S.C. § 1337(a)(1)(B)(ii) in 1988).

the strength of process patents, albeit not as great, by removing, with all of its advantages, the district court enforcement option.[41] The exceptions also fulfill the goal of limiting territorial overreach by not subjecting foreign companies whose products fall within the exceptions to personal liability for money damages.

Considering This Issue in the Context of Broader Patent Reform

If Congress decides to act on this issue, it should contemplate where it fits within the larger patent reform legislation that is currently before Congress. The § 271(g) exceptions issue is extremely complex, with the previous statutory reforms in this area requiring multiple attempts by Congress, a "bitter battle" between industries, and much congressional testimony.[42] The complexity of the issue stands in sharp contrast to the issue's lack of immediacy. If there is a problem, it is still only a potential problem. The Federal Circuit has yet to apply the dicta in *Kinik*. And the § 271(g) exceptions have even rarely been applied in district court cases since their 1988 adoption.[43]

Contrast all of this with the wider reaching patent reforms that address core patent issues currently before both the Senate and the House.[44] With such larger issues on the table, there is reason to think that Congress should not be distracted by the § 271(g) exceptions issue. Additionally, successful patent reform most likely requires compromise amongst the various constituents. To include another issue such as this one introduces another moving piece that may either upset the current balance in the pending legislation or make it more difficult to reach such a balance. To put it simply, the issue here may be too small, remote, and uncertain to justify Congress's immediate attention and energy and could possibly negatively impact the likelihood of passage of any broader reaching patent reforms currently before Congress.

Thank you for the opportunity to testify before you today. I would be pleased to answer any questions.

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[41] *See* S. Rep. No. 100-83, at 36-39 (noting all of the advantages of district court civil actions over ITC proceedings).

[42] *See Eli Lilly & Co. v. Am. Cyanamid Co.*, 82, F.3d 1568, 1579-81 (Rader, J., dissenting) (walking through the legislative history of 35 U.S.C. § 271(g)).

[43] *See* Li, *supra* note 3, at 639-40 (noting that the exceptions were applied only five times from their adoption until March 28, 2005).

[44] *See* Patent Reform Act of 2007, S. 1145, 110th Cong. (2007); Patent Reform Act of 2007, H.R. 1908, 110th Cong. (2007).

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May 18, 2007

The Honorable Patrick J. Leahy
Chairman,
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable Arlen Specter
Ranking Member,
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman and Senator Specter:

This letter provides the views of the Department of Commerce (DOC) and, in particular, its component the U.S. Patent and Trademark Office (USPTO) on the provisions of S. 1145, the "Patent Reform Act of 2007," as introduced.

This new patent bill is a revised version of legislation considered in the last Congress to modernize the U.S. patent system through changes designed to improve patent quality, reduce patent litigation costs and further international harmonization of patent laws. We support these goals.

INTRODUCTION

The bill includes reform proposals that would directly impact the USPTO. These include provisions on first-inventor-to-file, third-party submissions of prior art and post-grant review of patents. There are also litigation-management provisions relating to assessment of damages, willfulness determinations and venue considerations that do not directly impact USPTO operations, but rather patent policy in general.

There are also certain provisions that, while not currently in the bill as introduced, could usefully modernize the U.S. patent system. In the interests of providing as complete a picture as possible, we are including suggestions that are consistent with the goal of modernization.

In analyzing the provisions of S. 1145, and in suggesting additional items, we consider what will benefit U.S. inventors and the American public. It is from this perspective – benefit to Americans – that we approach our review and make recommendations.

QUALITY IS A SHARED RESPONSIBILITY

The U.S. patent system is predicated on disclosure. It cannot be emphasized enough that the grant of a patent right presumes an exchange of complete openness by the inventor for various rights of exclusivity. Thus, U.S. patent law requires inventors to disclose the "best mode" for reproducing their invention, and to explain their proposal in a manner clear to one skilled in a

particular art. We believe that emphasis on full disclosure – as is required for fair exchanges in all fields of enterprise – will ensure a vibrant, modern patent system.

A corollary of full disclosure must be intolerance for willful suppression or hiding of information. While, of course, fraud cannot be accepted, we also need a system that permits good-faith efforts to provide high quality and complete applications. The challenge for policymaking is to ensure modernization that both eliminates incentives for fraud and promotes full and complete applications.

I. Applicant Quality Submissions (AQSs)

Perhaps the most important element of ensuring that patent examinations are of the highest quality and processed as efficiently as possible is what the applicant files. The patent applicant has the most knowledge, the most opportunity, and the most to gain by providing the USPTO with the best possible information about his or her invention.

In the USPTO's new Accelerated Examination Program – where the first patent was issued in less than six months – applicants participate in an interview and provide the USPTO with a search and a support document. The USPTO's experience with this initiative is that both applicants and examiners realize that more written and oral information from applicants improves quality and timeliness.

The USPTO looks forward to taking the success of this model – captioned "applicant quality submissions" – to lower pendency, raise productivity and increase quality, and apply it to all patent examinations. To that end, the USPTO believes that applicants should be given every opportunity and the responsibility to provide more and better information to examiners about their inventions. For such a program to be successful, the USPTO will ensure that requirements for more and better information do not become overly burdensome in general and in particular to independent inventors and small entities.

We recognize that, in many cases, applicants have expressed strong concerns about providing the USPTO with complete information about their applications. In some cases, applicants simply do not want to provide important information for fear that it will limit the scope of the patent they may receive (though such a limitation would be proper under the facts and the law). Unfortunately, an additional percentage of applicants do not make the effort to fully define their inventions because there is currently no procedural or other deterrent to submitting an ill-defined application.

In some other cases, applicants or their attorneys fear that the legal doctrines of inequitable conduct and unenforceability may unfairly punish them with Draconian penalties for innocently omitting information. The theory is that if one provides information, he or she must do so perfectly or potentially lose the patent or face disciplinary action; whereas, a failure to share any information carries no consequences.

Under existing case law, a court that finds that an applicant has committed inequitable conduct in prosecuting a patent application must find unenforceable all claims of the patent and related

patents, even if they are otherwise valid. Thus, the only remedy available is a complete loss of the patent. Inequitable conduct can be found if the applicant deliberately withholds or inaccurately represents information material to patent prosecution. Anything the court deems that a reasonable examiner would find important can be material and the evidence necessary to show intent varies according to the nature of the omission. Accordingly, the inequitable conduct standard is uncertain and the potential penalties severe. For example, any misstatement in an affidavit, or even a failure to disclose a possible source of bias, has been held to be capable of rendering all claims of the patent unenforceable.

While the risk of an inequitable conduct finding is low, it is alleged relatively frequently and, when alleged, adds substantially to litigation costs and malpractice claims. The "all or nothing" result of an inequitable conduct finding understandably has a perverse effect on the actions of applicants and their attorneys with respect to "risking" a proper search in the first place. As a result, the doctrine drives counterproductive behavior before the USPTO. It discourages many applicants from conducting a search and leading others to be indiscriminate in the information they submit. In a review two years ago, we found that in over one-half of applications either no information disclosure statement was submitted or submissions included more than 20 references.

As we review and evaluate the elements of a successful and efficient AQSs program, we believe there are two related issues that would require legislative action, namely inequitable conduct and the ability of micro-entities to meet new information requirements.

(a) Inequitable Conduct

Consistent with the discussion above, DOC recommends that the bill be amended to address the doctrine of inequitable conduct and unenforceability to ensure that patent applicants are not discouraged from fully and fairly sharing relevant information with the USPTO.

Current uncertainties associated with the doctrine would be significantly reduced by clarifying the appropriate standards. First, the standard for finding intent could be explicitly separated from the materiality of the withholding, requiring proof that the misrepresentation was knowing, with intent to deceive. Second, the doctrine could be changed to a standard requiring a finding that the information would have been relevant to a reasonable examiner. The "relevance" standard could usefully be framed in terms of whether a reasonable examiner would have allowed the patent, without more, but for the misrepresentation or omission.

With respect to materiality, Congress may wish to consider requiring the USPTO to define the term (as it does now) and limit the courts to finding inequitable conduct only in circumstances in which information that the USPTO has defined as material is misrepresented or withheld.

DOC and the USPTO look forward to working with the Committee and stakeholders to develop provisions that would be more effective than the current doctrine in facilitating the targeting of fraud that actually affects the examination process and in improving the quality of applicant submissions.

(b) Micro-Entity Status

We recognize that any AQSs program with requirements for more and better information must not become overly burdensome in general and in particular to independent inventors and small entities.

Accordingly, with respect to truly independent inventors and truly small entities, DOC recommends that the bill be amended to define a "micro-entity" status. The definition could be based on a number of factors including: income level; number of patent applications filed; lack of representation by a registered practitioner; and lack of assignment activity. The status would exempt an applicant from some or all of the requirements of an AQSs program.

That status also could be used to identify inventors eligible for reduced fees and other preferred treatment and assistance.

2. Prior Art Submissions

Section 9(b) of the bill expands the ability of third parties to submit information they believe is pertinent to a pending application. Specifically, the proposal would permit the submission of patents, published applications or other printed publications before the earlier of: (1) the mailing date of a notice of allowance, or (2) either six months after pre-grant publication, or the date of the first rejection of any claim by the examiner, whichever occurs later.

This proposal is consistent with the discussion above regarding AQSs and overall efforts to encourage a highly participatory examination process with more engagement by applicants as well as by other interested parties with information relevant to that examination.

Current USPTO rules permit submission of patents or printed publications within two months of publication or before the mailing of a notice of allowance, whichever occurs first.

In contrast to current USPTO rules, the bill would require that the submission include a "concise description of the asserted relevance of each submitted document." Current USPTO rules do not permit inclusion of comments or explanations concerning the submitted patents or printed publications.

DOC supports enactment of this section, with minor revisions, and anticipates that the provisions will serve to provide our examiners with information they may not otherwise obtain and should result in a more efficient examination process and a higher quality, more reliable patent. We have identified a few technical revisions that should be made prior to enactment and recommend that the provision be accompanied by regulatory authority for the Director of the USPTO to implement procedural requirements to make the submission process as efficient as possible.

Consistent with the provisions and rationale of this section, the USPTO is cooperating in a pilot program involving peer review of patent applications. Up to 250 applications, assigned to Technology Center 2100, which examines computer-related technologies, will voluntarily be placed, by the applicants, on a non-USPTO web site for an expanded and public review by a peer

group of patent users, attorneys and academics. The pilot group of applications will include applications filed by small entity filers. The public group will determine and submit to the USPTO what they consider the best available and relevant prior art. The pilot program will test whether this peer review can effectively identify prior art that might not otherwise be found by our examiners during the typical examination process. We will also make an evaluation as to whether this process results in measurable examination timesavings and quality improvements.

LITIGATION MANAGEMENT ITEMS

The disclosure philosophy has even more relevance to litigation than to examination, as it exposes the economic repercussions of a failure to fully disclose. One of the purposes of the patent system authorized by the Constitution of the United States is to promote the dissemination of knowledge to the public through disclosure of inventions. Requirements for more and better information to support a patentability determination are comparable to current requirements in virtually every judicial and administrative proceeding for parties to bring the most relevant, reliable and complete information before the decision-making body.

We fully appreciate that not all industries are similarly situated, that market conditions change over time, and that practical matters – such as channels of trade – may be legitimate factors for consideration in a patent-infringement case. Therefore, we believe it is critical that litigation-management modernization efforts preserve discretion for courts that enables them to account for differences across industries, markets, and time.

3. Apportionment of Damages

Section 5(a) of the bill, in part, directs the court to ensure that a reasonable royalty is applied only to the economic value attributed to the patented invention as distinguished from the economic value attributable to other features added by the infringer. More specifically, the bill also provides that in order for the entire market rule to apply, the patentee must establish that the patent's specific improvement is the predominant basis for market demand.

Current patent law provides that a patentee is entitled to damages adequate to compensate for infringement, but in no event less than a reasonable royalty. The question of what is the value of a relatively small piece of patented technology when it is integrated as a component of a larger article has attracted substantial attention by the high-tech industry.

Under the entire market rule, the value of the entire apparatus, which includes both patented and other inventions not covered by the patent at issue, is used as the royalty base for computing reasonable royalty.

Concerns have been expressed that patent awards based on the entire market value are overly generous. Legislative proposals have attempted to solve this problem by directing courts to consider the contribution of other elements of the entire product added by the infringer. This is one of several factors, commonly referred to as the *Georgia-Pacific* factors, typically considered by courts in determining royalty rates.

While the appropriateness of damages awards in a number of patent cases may be subject to debate, DOC does not believe that a sufficient case has been made for a legislative provision to codify or emphasize any one or more factors that a court must apply when determining reasonable royalty rates. Further evaluation or research is necessary to determine whether a statutory "entire market rule" may not be readily or appropriately applicable to technology that involves something other than a physical component of a product.

It appears that the courts have adequate guidance through *Georgia-Pacific* and, as a general matter, do in fact consider numerous factors in determining royalty rates, including: rates paid by other licensees; nature and scope of the license; profitability of the product; commercial relationship between the licensee and licensor; as well as the portion of the realized profit attributable to the invention. The amount of a reasonable royalty should turn on the facts of each particular case, as best as those facts can be determined.

4. Willful Infringement

Section 5(a) of the bill, in part, limits a court's ability to award enhanced damages in the following ways: (1) codifies that increased damages are limited to instances of willful infringement; (2) requires a showing that the infringer intentionally copied the patented invention; (3) requires notice of infringement to be sufficiently specific so as to reduce the use of form letters; (4) establishes a good faith belief defense; (5) requires that determinations of willfulness can only be made after a finding of infringement; and (6) requires that determinations of willfulness be made by the judge, not the jury.

Willful patent infringement can certainly have significant consequences. The court may treble the damages and award attorney fees. With escalating patent litigation costs, the threat of treble damages can be quite substantial. Some have expressed concerns that willfulness is frequently alleged as a matter of course and alleged infringers have to bear the expense of defending such actions.

While there is some evidence to support the claim that willfulness is frequently alleged, the evidence also suggests that willfulness is currently difficult to establish. The additional requirements, limitations, and conditions set forth in the bill may significantly reduce the ability of a patentee to obtain treble damages.

Modernization efforts should avoid perverse incentives that might make infringement simply "a cost of doing business." While not the only deterrent to patent infringement, the possibility of treble damages provides an important and substantial obstacle -- more than might be seriously considered in a practical business calculus.

For lack of a clear and substantiated case for major statutory reform in this area, DOC is unable to support all the provisions of section 5(a) of the bill as currently drafted. However, DOC can support a number of the narrowly drawn provisions of the section that we believe are appropriate, reasonable and fair to most interested parties.

Accordingly, the Department supports enactment of the amendments contained in section 5(a) that statutorily limit enhanced damages to determinations of willful infringement; require sufficiently specific notices of infringement; and provide that an inference of willfulness can not be drawn from the decision of an infringer not to present evidence of advice of counsel.

5. Prior User Defense

Section 5(b) of the bill expands the prior use defense, created by the American Inventors Protection Act of 1999, by eliminating the limitation that the subject claim be directed to a "method of doing or conducting business." It also enhances the safe harbor for non-patentees in that they would only have to show commercial use, or substantial preparations for commercial use, at any point before the effective filing date of the patent application (rather than that date plus one year).

The benefit of a prior use defense is clearly directed toward the non-patentee. Proponents argue that this is reasonable in a competitive economy and strikes a balance between trade secret and patent protection.

Critics argue that prior user rights undermine the purpose of a patent system by creating a strong incentive to protect innovations as trade secrets. Under a prior use defense regime, if inventors are able to protect their innovations as trade secrets, they are able to use them indefinitely, even if someone else obtains a patent on the invention.

Absent a change to a first-to-file system, DOC does not support the bill's expansion of the prior user defense at this time. The existing defense has rarely been invoked and there is insufficient information to gauge the potential impact of substantially expanding it.

6. Venue

Section 10(a) of the bill limits the places where corporations may be sued by amending 28 U.S.C. § 1400(b) to provide that a corporation "resides" only where it has its principal place of business or in the State in which the corporation is incorporated.

This provision is clearly more restrictive than the current "personal jurisdiction" standard that requires "minimum contacts" for venue purposes and represents a substantial departure from established practice. While this proposal addresses forum shopping concerns expressed by many patent owners, it may not result in the most appropriate and convenient venue for litigation.

Also, the proposal expands the types of actions subject to 28 U.S.C. § 1400(b) which currently is limited to patent infringement actions. The proposal would cover any civil action arising under any federal law relating to patents, other than declaratory judgment and Patent Board decisions.

DOC has not taken a position on the provisions of this section. We will review and evaluate the proposal, along with possible alternatives, in consultation with the Department of Justice.

APPEALS

7. Interlocutory Appeals

Section 10(b) of the bill provides that parties in a patent infringement suit are permitted to have an interlocutory appeal to the Court of Appeals for the Federal Circuit after a *Markman* hearing on claim construction, rather than waiting for a final judgment to be rendered by a district court.

While proponents of this provision maintain that these appeals would reduce the length and cost of litigation, others believe that the appeals may have the opposite effect and would in fact offer "another bite at the apple" because the reversal rate for claim construction is fairly high.

DOC is unable to support this provision at this time. We will consider the merits in consultation with the Department of Justice.

PROPOSALS DIRECTLY AFFECTING THE USPTO

8. Post-Grant Review

Section 6 of the bill establishes post-grant review procedures under which any person may request the USPTO to cancel as unpatentable any claim of a patent: within 12 months after issue or reissue; when the petitioner establishes a substantial reason to believe that the continued existence of the challenged claim causes or is likely to cause the petitioner significant economic harm; or when the petitioner has received notice from the patent holder alleging infringement by the petitioner.

Post-grant review procedures would be more expansive than existing reexamination procedures and would include consideration of evidence gleaned through depositions and interrogatories as well as patents and other documents. A newly designated Patent Trial and Appeal Board would be responsible for conducting the post-grant reviews.

The USPTO Director would prescribe regulations establishing and governing the proceedings including standards for showings of "substantial reason to believe" and "significant economic harm" and procedures for the submission of supplemental information and discovery of relevant evidence. The Director would also establish by regulation reasonable fees to be paid by the person requesting the proceeding.

Final determinations would be issued within one-year with a six-month extension available for good cause shown. Regulations would address sanctions for abuses of the proceedings.

Many aspects of the post-grant review section are similar to those contained in the draft bill prepared by the USPTO in 2005. A primary difference is the scope of the "second window." While the USPTO's proposal would also provide for a one-year first window, it would limit the second window to a six-month period after receipt of a notice from the patent holder alleging infringement. Additionally, the USPTO proposal would authorize the Director to promulgate

regulations that would also require a petitioner to show substantial economic harm. That authority would enable the USPTO to control or limit an influx of potential cases.

A second significant difference is that the bill's applicability reaches back to patents issued before the effective date of the legislation. The USPTO's procedures would be available only on a prospective basis.

The broad scope of the bill's second window coupled with the substantial number of patents subject to the proposed review procedures create very legitimate concerns about the USPTO's ability to effectively handle the potential workload. Accordingly, while the Department supports the establishment of post-grant review procedures, we suggest revision of the bill's provisions to more closely align with those in the USPTO's draft bill. We would be pleased to work with the Committee in that regard.

9. USPTO Regulatory Authority

Section 11 of the bill would specifically authorize the USPTO to promulgate such rules, regulations and orders that the Director determines appropriate to carry out the provisions of Title 35 or any other applicable law or that the Director determines necessary to govern the operation and organization of the USPTO.

We thank Congress for suggesting appropriate authority for the USPTO. The USPTO has long believed that rulemaking authority is beneficial to the patent system, and welcomes authority that is necessary to promulgate regulations to ensure an efficient and quality-based patent examination process. We have concerns about unbounded discretion, and therefore want to be certain that any grant is not overbroad.

10. First Inventor to File

Section 3 of the bill converts the U.S. patent system from a first-to-invent to a first-inventor-to-file system and makes various conforming amendments. A grace period is provided to promote an inventor's disclosure of the subject matter of the claimed invention without loss of priority. Interference proceedings are replaced with a derivation proceeding to determine whether the applicant with an earlier-filed application is the proper applicant for the claimed invention.

While the rest of the world uses a first-to-file system, the United States continues to award a patent to the first to conceive an invention, provided that all patentability criteria are satisfied. Proponents of first-to-file maintain that it would simplify the patent process, reduce legal costs, improve fairness and enhance the opportunity to make progress toward a more harmonized international patent system.

Opponents of first-to-file are concerned that adoption of first-to-file could promote a rush to the USPTO with hastily prepared disclosure information resulting in a decline in quality. Also, because many independent inventors and small entities lack sufficient resources and expertise, they feel that they would be unlikely to prevail in a "race to the patent office" against large, well-endowed entities.

Conversion to a first-to-file system has been advocated by various interest groups in the United States for decades. It is still the subject of continuing controversy. While DOC recognizes the potential benefits of a first-to-file system, we do not support immediate conversion to first-to-file via this legislation.

It should be noted that U.S. conversion to first-to-file is an overriding consideration in ongoing substantive patent law harmonization discussions with foreign patent offices. We hope those discussions will lead to significant benefits for patent applicants and promote work sharing among worldwide patent offices. In this regard, we believe that any U.S. commitment to convert to first-to-file should be contingent on significant progress and international agreement in those harmonization discussions. In particular, the United States seeks a standardized one-year international grace period to protect American inventors who might disclose their invention prior to filing for a patent.

Additionally, with respect to the specific text of section 3 of the bill, DOC has identified a number of concerns regarding the scope and application of provisions relating to prior art and grace period that may require revision and clarification.

11. Assignee Filing

Section 4 of the bill proposes several changes to current practice regarding who must or may file an oath or declaration in a patent application and the application itself. A person to whom an inventor has assigned or is under an obligation to assign the invention would be able to make an application for a patent. Current practice requires that, as a general matter, applications must be filed by the inventor(s).

DOC and most members of the patent community generally favor simplifying and streamlining patent application procedures and reducing any unnecessary formalities. The proposal is an appropriate step in that direction. While the Department supports adoption of these provisions, we have identified a number of technical issues in the text of section 4 that should be addressed and clarified as the legislative process continues. Those issues relate to specific entitlement to the grace period and national security and transparency considerations.

12. 18-Month Publication

Section 9(a) of the bill eliminates the current opt-out provision for publication of patent applications. Current law permits an applicant to request upon filing that his or her application not be published at 18-months if a certification is made that the invention disclosed in the application has not and will not be the subject of an application filed in another country that requires such publication.

DOC is hesitant to support this provision at this time considering that the current opt-out provision is a result of the careful balancing and sensitive negotiations that took place during the legislative process that led to the enactment of the American Inventors Protection Act of 1999. It addresses the serious concerns expressed then and now by independent inventors and small

entities that large entities and foreign interests may misappropriate their inventions upon disclosure and prior to issuance of a patent.

CONCLUSION

Thank you for this opportunity to share our views on this important piece of legislation. DOC looks forward to working with the Committee and the Congress to develop legislation that improves our patent system, while maintaining the balance among the interests of patent applicants, relevant third parties, the general public, and the information needs of the USPTO to serve all three. The Office of Management and Budget has advised that there is no objection to the transmittal of these views from the standpoint of the Administration's program. If you have any questions, please contact me or Nat Wienecke, Assistant Secretary for Legislative and Intergovernmental Affairs, at 202-482-3663.

Sincerely,

John J. Sullivan

cc: All Members of the Senate Judiciary Committee

April 30, 2007

Statement for Hearing on
"Process Patents"
Senate Judiciary Committee
May 1, 2007

I would like to thank both the Chairman and the Ranking Member for holding this hearing on patent reform and specifically on the issue of process patent protections.

Patent reform is clearly needed. While various industries may differ over specifics, all agree some reform is necessary. I know that this is one of the Chairman's priorities for this session of Congress and I look forward to working with him to examine how best to improve patent quality and the patent system.

I also want to thank the Chairman for his cooperation and willingness to work with me on the issue that is being discussed at today's hearing.

The recently introduced patent reform bill maintains current law on process patents and upholds Congressional intent for how to deal with disputes over products that use processes that have been patented in the United States, but then are manufactured outside the United States.

In February of this year, I sent a letter to Chairman Leahy and Senator Hatch, before they introduced their bill asking them to uphold current law on this issue, and I am pleased they did.

When process patent law was passed in 1988 to allow patent holders to enforce their rights in U.S. courts, Congress created two defenses that could be asserted. At the same time, however, Congress made it clear that the two defenses were only available in cases before a U.S. court, and were not going to be available in the International Trade Commission (ITC) – this is found at 35 U.S.C 271(g).

The patent reform bill as introduced maintains this section of the code.

Some have argued that it is important to change the law to try to make the affirmative defenses equally available in both U.S. courts and at the ITC.

While in a vacuum this may sound logical, the reality is that such a change would have harmful consequences.

If the law were changed, the effect would be to make it easier for foreign manufacturers to infringe upon a U.S. process patent by providing them with defenses that would not be available to a domestic company that took the same actions and infringed on a process patent.

Making this change, could then encourage nefarious actors to simply manufacture their products overseas in order to avoid paying licensing fees to U.S. patent holders – allowing these manufactures to have an unfair advantage when competing with U.S. made products that comply with patent holder's rights.

Ultimately, this change would undermine the value of U.S. process patents, and I believe have a detrimental effect on U.S.-based manufacturing jobs by allowing foreign manufacturers to import and sell products here that infringe on a U.S. process patent.

This is not good policy and would undercut congressional efforts to protect American jobs.

With California's large and diverse high-technology business sector, growing bio-technology industry, and

innovative university research centers, any change in our patent law could have far-reaching effects impacting many companies and workers in my home state.

So I believe any changes must be well thought out and carefully implemented.

I have heard concerns about this proposed change from inventors and universities from California.

In addition, this change is opposed by the Intellectual Property Owners Association, the American Intellectual Property Law Association, the American Council on Education, the Association of American Universities, and the AFL-CIO.

I would like to submit letters for the record opposing this change.

Finally, I again want to thank you Mr. Chairman for holding this hearing.

I appreciate your's and Senator Hatch's leadership on patent reform and appreciate your leadership on protecting this provision of the law.

Hearing on "Process Patents"

Before the United States Senate
Committee on the Judiciary
May 1, 2007

Wayne W. Herrington
Assistant General Counsel
United States International Trade Commission

Chairman Leahy, Ranking Member Specter, and Members of the Committee: The Commission appreciates the opportunity to appear before this Committee to discuss its administration of section 337 of the Tariff Act of 1930 and process patents.

The Commission is an independent, nonpartisan, quasi-judicial agency. It administers a wide variety of trade-related statutes, including Section 337 of the Tariff Act of 1930 (19 U.S.C. § 1337). Section 337 prohibits unfair practices in the import trade, including imports which infringe intellectual property rights. In fact, the overwhelming majority of our cases under section 337 involve allegations of patent or trademark infringement, with allegations of patent infringement predominating. We conduct our section 337 proceedings under the adjudicative provisions of the Administrative Procedure Act, with an administrative law judge making an initial determination and the Commission making the final determination. If the Commission finds a violation of section 337, it may issue an order excluding the infringing products from entry into the United States. It may also issue cease and desist orders to infringing firms and persons prohibiting them from selling infringing goods already located in the United States.

The subject of this hearing is the law applicable to the unauthorized importation and sale of products made abroad by a process covered by the claims of a United States patent. The Commission has had statutory authority to address such unauthorized importation since 1940,

when Congress enacted what used to be known as section 337a (former 19 U.S.C. § 1337a), a free-standing provision which was intended to overrule the decision of the Court of Customs and Patent Appeals (now the Federal Circuit) in *In re Amtorg Trading Corp.*, 75 F.2d 826 (CCPA 1935). Section 337a was eventually incorporated in section 337 itself as section 337(a)(1)(B)(ii) as a result of the amendments to section 337 in the Omnibus Trade and Competitiveness Act of 1988 (Public Law 100-418, § 1342(a)(1)). The history of this provision relating to process patents is summarized in the decision of the Federal Circuit in *Amgen, Inc. v. U.S. International Trade Commission*, 902 F.2d 1532 (Fed. Cir. 1990). The current version of section 337(a)(1)(B)(ii) provides that the importation, sale for importation, or sale within the United States after importation of a product will be a violation of section 337 if it is "made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent."

The U.S. district courts did not obtain statutory authority under the patent law to address the unauthorized importation and sale of products made abroad by a patented process until 1988, when 35 U.S.C. § 271(g) was added to the patent law by the Process Patent Amendments Act, which was enacted as part of the Omnibus Trade and Competitiveness Act (Public Law 100-418, §§ 9001-07)). Section 271(g) provides in pertinent part that "[w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of the process patent...." Section 271(g) also provides that "[a] product which is made by a patented process will, for purposes of this title, not considered to be so made after–(1) it is materially changed by

subsequent processes; or (2) it becomes a trivial and nonessential component of another product."

In 2002, the Commission affirmed an order of one of its administrative law judges that the defenses to infringement contained in 35 U.S.C. § 271(g), *i.e.*, section 271(g)(1) and (2), were not available in a case based on section 337(a)(1)(B)(ii) and that those defenses had not been timely raised. *Certain Abrasive Products Made Using a Process for Powder Preforms, and Products Containing Same*, Inv. No. 337-TA-449 (Commission Opinion Affirming ALJ Order No. 40). In making its decision, the Commission noted that section 9003 of the Process Patent Amendments Act added section 271(g) to the patent law. However, the Commission found that section 9006(c) of the Process Patent Amendments Act made it clear that the defenses of section 271(g)(1) and (2) would not apply to section 337 cases because section 9006(c) provided that "[t]he amendments made by this subtitle shall not deprive a patent owner of any remedies available...under section 337 of the Tariff Act of 1930, or under any other provision of law." As an additional reason, the Commission found that section 271(g) explicitly restricted its application to cases under Title 35 because it expressly stated that the exceptions to infringement in sections 271(g)(1) and (2) were "for purposes of this title [Title 35]" and thus that those defenses do not apply to cases brought under section 337, which is part of Title 19.

The accused infringer in the *Abrasives* case, Kinik Co., appealed the Commission's final determination to the Federal Circuit, arguing numerous points, including that the Commission erred in holding that Kinik could not rely on the defenses in section 271(g)(1) and (2). On appeal, the Federal Circuit agreed with the Commission's interpretation of the statutory provisions and the legislative history with respect to the inapplicability of the section 271(g)

defenses. *Kinik Company v. International Trade Commission*, 362 F.3d 1359 (Fed. Cir. 2004). However, the Court reversed the Commission's finding of infringement on an entirely unrelated basis because it disagreed with the Commission's claim construction. *Id.*

The foregoing is a summary of the Commission's practice and the development of the law. The Commission would be pleased to provide technical advice on any language the Committee may be considering.

Pet Food and Pool Cues

By **MICKEY KANTOR** and **THEODORE B. OLSON**
May 13, 2006; Page A9

As Mr. Bumble said in "Oliver Twist," "If the law supposes that, the law is a ass, a idiot." How else to describe squarely contradictory interpretations of U.S. laws, under which a federal court applying the patent laws can find a product to be non-infringing and permit its importation and sale -- while another federal tribunal may simultaneously prohibit the importation of that same product on the ground that it infringes?

Such an incongruous and capricious application of our laws makes no sense, keeps legal products from consumers, stifles competition and holds our trade practices and policies up to ridicule and retaliation from our trading partners and international organizations. It is costly, irrational, invites forum-shopping -- and Congress should move promptly to fix it.

This anomaly in our trade policy results from a split between two tribunals chartered to adjudicate patent disputes, particularly those involving so-called "process patents." Over time, as products have become more complex, patent laws have been revised and expanded to protect inventors when their product is used as a component in another product -- and patent protection has also been extended to the processes by which products are made.

But Congress has carefully defined the scope and enforceability of process patents so that they do not inhibit otherwise lawful and commercially desirable activity. Thus, a product does not infringe a process patent if it has been materially changed by subsequent steps in the manufacturing process or if the product is merely a trivial and nonessential component of another, more complex, product.

The logic behind these limitations is easy to understand: There is no real harm done to the holder of a process patent if someone produces and imports a significantly different product or a product in which the component produced by the patented process is essentially immaterial to the final product. On the other hand, real damage to the economy and to innovation could ensue if these limitations were not built into the law. The patent holder would hold enormous leverage and blocking power over products that have little or nothing to do with his invention. Such unnecessary and counterproductive monopolies chill innovation and are disfavored by the law.

Federal courts have embraced these clear congressional limits on the scope of process patents. But one very powerful agency has not. The International Trade Commission, an entity charged primarily with enforcing customs and imports laws and largely unknown to the American public, has concluded that it may ignore these limitations and exclude from importation any product that results from the use of a patented process even if, under the statutory definition, it does not infringe on the patent. In other words, for imported products the validity and enforceability of a process patent means one thing in patent infringement cases in federal court and another in ITC exclusion proceedings.

The ITC came to this anomalous conclusion by reasoning that, while the scope of the patent was defined by the patent laws, the ITC could ignore those statutory limits when exercising its authority to exclude a product from the U.S. when its importation would

constitute an "unfair trade practice." The result: A product may be barred from the U.S. by the ITC even though it does not infringe on any patent under the patent laws.

This interpretation is, to put it bluntly, nonsense, exalting form over substance, logic and common sense. The beneficiaries are manufacturers who fear competition from imported products that may conveniently be excluded from the domestic market by the ITC's Orwellian legal reasoning. The losers are lawful importers and American consumers who may desire to purchase the banned product or benefit from the lower prices that flow from a competitive marketplace.

This bizarre policy affects American and foreign companies alike. Many American manufacturers import products assembled abroad; and many non-American companies assemble products here from imported components. Virtually every industry imaginable has already been or could be affected -- from pet food to semiconductors to pharmaceuticals to pool cues.

The U.S. lost a bitter trade battle -- 20 years ago -- over this very same kind of unfair treatment of imports in ITC patent cases. An international panel concluded that the ITC's procedures discriminated against imports in violation of international treaties. In the years since, Congress has twice amended U.S. laws in response to adverse findings by international tribunals in order to ensure that we do not discriminate against imports.

By asserting the authority to ban imports that do not violate substantive U.S. patent laws, the ITC has once again set the stage for a losing battle with our trading partners. A recent draft report by the European Commission has expressed concern over ITC policies adversely affecting European companies and U.S. barriers to imports. It does not take a crystal ball to see where this latest controversy is headed: another defeat for U.S. trade policy followed by an inevitable and somewhat humiliating need for a legislative correction. We cannot expect our trading partners to deal fairly and without discrimination toward products we export when we apply such arbitrary, irrational trade policies to imported goods.

Fortunately, Congress could easily fix the problem by making it clear it meant what it said and said what it meant when it carefully defined the scope of process patent. This is a legislative fix that will be resisted only by those companies that are afraid of legitimate, lawful competition. It would be prudent for the ITC to reconsider or for Congress to make the change before it is forced upon us by an adverse decision by an international tribunal. Until it does, we will be perceived as Humpty Dumpty in "Through the Looking Glass." "When I use a word," he said, "it means just what I choose it to mean -- neither more nor less." Alice's response: "the question is whether you can make words mean so many different things."

Mr. Kantor was secretary of commerce and U.S. trade representative during the Clinton administration. Mr. Olson was solicitor general during the George W. Bush administration. They represent Hoffmann-La Roche Inc., which is seeking changes in the ITC's position on process patents.

AIPLA

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Statement of

Michael K. Kirk
Executive Director
American Intellectual Property Law Association

Before the

Committee on the Judiciary
United States Senate
Washington, D.C.

On

Process Patents

May 1, 2007

Mr. Chairman:

I am pleased to have the opportunity to present the views of the American Intellectual Property Law Association (AIPLA) on the topic of process patents, and specifically the question of whether the defenses to infringement in Section 271(g) of title 35 should be made applicable to Section 337 of the Tariff Act of 1930. AIPLA appreciates the opportunity to comment on this issue.

AIPLA is a national bar association of more than 17,000 members engaged in private and corporate practice, in government services, and in the academic community. AIPLA represents a wide and diverse spectrum of individuals involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. Since our members represent inventors before the PTO, as well as both plaintiffs and defendants in patent litigation, we have a keen interest in reforms that further an efficient, effective, and balanced patent system.

Summary

AIPLA opposes legislation that would amend Section 271(g) of the Patent Act, 35 U.S.C. § 271(g), in a manner that would undermine the existing rights of process patent owners to obtain relief against unfair trade practices under Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337(a)(1)(B)(ii), as enforced by the United States International Trade Commission (ITC). Specifically, AIPLA opposes efforts to amend Section 271(g) that would weaken the ability of United States process patent owners to enforce their rights against the importation of foreign-manufactured products by providing those foreign manufacturers with additional defenses in Section 337 proceedings brought in the ITC.

Section 337 proceedings in the ITC have long been an effective means of protecting domestic industry against the importation of products manufactured abroad by a process protected

by a U.S. process patent. The Process Patents Amendments Act of 1988 ("PPAA"), which added Section 271(g) to the Patent Act, was intended to strengthen process patent rights, not to weaken the rights of process patent owners, as would be the case if Section 271(g) were amended as proposed.

Such a diminishment of process patent rights would put United States industry at a disadvantage with respect to their foreign competitors, by increasing the ability of foreign manufacturers to practice United States process patents abroad, and then import the products made by the patented process for sale in the United States. It would encourage off-shoring by creating a perverse incentive to export manufacturing processes and jobs to foreign countries, where the rights of United States process patent owners could be ignored, directly contrary to the purpose of the PPAA. For these reasons and those explained more fully below, AIPLA opposes the proposed amendment to Section 271(g) of the Patent Act and efforts to undercut the longstanding rights of United States process patent owners to seek the ITC's assistance in protecting established domestic industries by issuing Exclusion Orders against unfair trade practices and barring the importation and sales of products made by infringing processes practiced outside the United States.

Background

Section 271(g)

Section 271(g) provides:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a

patented process will, for purposes of this title, not be considered to be so made after—

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

35 U.S.C. § 271(g).

Section 271(g) was added to Title 35 of the United States Code by the Process Patents Amendments Act of 1988 (PPAA), which was part of the Omnibus Trade and Competitiveness Act of 1988. According to the legislative history of the PPAA, the concerns about infringement of United States process patents by manufacturers in foreign countries that gave rise to the passage of the PPAA date back to 1966 and can be found in President Johnson's Commission on the Patent System. *See "To Promote the Progress of ... Useful Arts"*, Report of the President's Commission on the Patent System 35-36 (1966).

Section 271(g) contains two specific defenses to infringement of United States process patents by the practice of processes outside the United States. Such activity does not constitute infringement "for purposes of this title" – *i.e.*, under Section 271(g) – if the product made by the patented process is "materially changed by subsequent processes" or "becomes a trivial and nonessential component of another product." These specific defenses were newly-created with the passage of the PPAA; they appear nowhere else in the Patent Act and have no history in the statute or patent jurisprudence. More than a decade after their creation, they have been only rarely discussed in reported decisions and they remain poorly defined and notoriously fact-specific.

Section 337 Proceedings in the ITC

Before passage of the PPAA, an owner of a process patent in the United States was able to enforce its patent in the United States federal courts under 35 U.S.C. § 271 only if all steps of the process took place within the United States. Before the PPAA, the only remedy available to a process patent owner for the importation of a product manufactured by the patented process was

an order from the ITC excluding the product from entry into the United States under Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337(a)(1)(B)(ii), which provides in pertinent part:

> (a) *Unlawful activities; covered industries; definitions.—*
>
> (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
>
> * * *
>
> (B) The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that—
>
> * * *
>
> (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

The ITC is thus authorized to issue Exclusion Orders in Section 337 proceedings to protect domestic industry against importation of products made by a process practiced abroad that would infringe a valid and enforceable United States process patent claim if practiced in the United States. The ITC's Exclusion Orders are enforced by United States Customs, and are subject first to Presidential review, and then to review by way of appeal to the United States Court of Appeals for the Federal Circuit.

There are significant differences between a Section 337 proceeding in the ITC and an action for patent infringement in federal court. An action in federal district court is a civil proceeding between private litigants, but because the ITC is charged with protecting the public interest and domestic industry, the Commission is a party to a Section 337 investigation and its staff are active participants throughout the process. They investigate the allegations in the complaint, determine whether to institute an investigation, actively engage in the discovery process, motion practice and other pre-trial proceedings, present evidence and argument at trial, and brief and argue post-trial motions and any appeal. To prevail in a Section 337 action, the

patent owner must show not only use of a process covered by a valid, enforceable claim of a process patent, but also that it has created a domestic industry that would be harmed by the importation. In addition, the patent owner also must show that the public interest would be served by the issuance of an Exclusion Order. Finally, no damages are awarded in a Section 337 proceeding. The Exclusion Order and related Cease and Desist Orders are the sole remedies available in Section 337 proceedings.

Congress enacted the PPAA after years of debate and numerous compromises. The PPAA was intended to give the owners of United States process patents the ability to seek injunctive relief and damages in federal court against infringers who were evading process patents by practicing some or all of a patent process overseas and then importing the resulting product for sale in the United States. The PPAA represented an effort to place domestic manufacturers on a more level playing field with foreign manufacturers, and to eliminate any incentive to export manufacturing processes and jobs to evade United States process patents.

It is clear that in passing the PPAA, Congress intended Section 271(g) to provide additional remedies in federal court for process patent owners. Congress explicitly stated that it in no way intended to supplant or undermine any existing rights or remedies available to patent owners under any other subsection of 35 U.S.C. § 271 or in Section 337 proceedings brought in the ITC. Subsection (c) of Section 6 of the PPAA could not be clearer on this point:

> Retention of Other Remedies.—The amendments made by this subtitle shall not deprive a patent owner of any remedies available under subsections (a) through (f) of section 271 of title 35, United States Code, under section 337 of the Tariff Act of 1930, or under any other provision of law.

Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, § 9006(c), 102 Stat. 1107, 1567 (1988).

The legislative history on this point is equally clear. Addressing the provision codified as Section 271(g), the Senate Report states:

> Section 105(b) makes clear that the bill does not affect any remedies patent owners have under existing law. The new remedies for process patent owners provided by the bill are subject to general limitations which do not apply in suits under existing law by process patent owners against parties manufacturing in the United States. For example, . . . [t]he bill provides that a product which is made by a patented process will not be considered so made after it is materially changed by subsequent processes; or it becomes a trivial and nonessential component of another product. There is no intention to impose any of these limitations on owners of product patents or on owners of process patents in suits they are able to bring under existing law. *Neither is there any intention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.*

S. Rep. No. 100-83 at 60-61(1987) (emphasis added).

Consistent with the language of the statute and its legislative history, in *Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359 (Fed. Cir. 2004), the ITC held, and the Federal Circuit affirmed, that the PPAA did not create new defenses for respondents in Section 337 proceedings brought in the ITC. Specifically, the Federal Circuit affirmed the ITC's holding that the two specific defenses to infringement under Section 271(g) – exempting a product made by a patented process if that product is "materially changed by subsequent processes" or "becomes a trivial and nonessential component of another product" – do not apply in Section 337 proceedings before the ITC.

Discussion

AIPLA opposes any amendment to Section 271(g) that would undermine the longstanding rights of United States process patent owners to seek the ITC's assistance in protecting established domestic industries by issuing Exclusion Orders against unfair trade practices and barring the importation and sales of products made by infringing processes practiced outside the United States. Specifically, AIPLA opposes any amendment to Section 271(g) that would apply the two specific defenses to infringement under Section 271(g) – exempting products made by the patented process from infringement if such products are "materially changed by subsequent

processes" or "a trivial and nonessential component of another product" -- to Section 337 proceeding before the ITC.

Section 337 proceedings in the ITC have a separate statutory basis from patent infringement actions brought in federal court. Section 337 proceedings, which existed long before the PPAA was enacted, are intended to protect domestic industries and the public interest by empowering the ITC to launch investigations and issue Exclusion Orders against unfair trade practices, invoking the protection of United States Customs to stop the future importation of goods made offshore by practicing United States process patents. Unlike federal court actions, ITC proceedings do not adjudicate disputes between private litigants, award damages to redress past infringement, or decide reasonable royalties for future infringement if a permanent injunction is not issued.

Because ITC and federal court actions have different purposes and involve different remedies, there is nothing inconsistent with Congress' decision, in passing the PPAA, not to extend the two specific, newly-created defenses to infringement under Section 271(g) to the pre-existing requirements for Section 337 proceedings in the ITC. For example, one fundamental difference between the ITC and a federal court is that the ITC can only issue orders preventing future unfair trade practices, whereas a court can award damages for past infringement. In enacting the PPAA, Congress concluded that it would not be appropriate to subject a defendant in federal court to a damages award for sales of products made overseas by a patented process if those products were "materially changed by subsequent processes" or were "a trivial and nonessential component of another product." But Congress did not conclude that Section 337 should be amended to permit a foreign manufacturer to escape an exclusion order for importing such products into the United States where either of the two conditions applies.

Prior to passage of the PPAA in 1988, offshore manufacturers who followed the teachings of United States process patents to manufacture products for importation and sale in the United States could be blocked by an ITC Exclusion Order. There were no special defenses allowing the continued importation or sales of products made overseas by a patented process if those products were "materially changed by subsequent processes" or "a trivial and nonessential component of another product." But offshore manufacturers importing such products into the United States were not subject to liability for damages in a federal court patent infringement action. Congress closed that loophole with passage of the PPAA, making those infringers subject to damages liability for their past infringement, subject to two specific defenses. But in closing that loophole, Congress was careful not to undermine the protection available under Section 337 by giving respondents in ITC proceedings new defenses to the issuance of Exclusion Orders against future importation of products made abroad by infringing processes. AIPLA believes that Congress should not create such a loophole to the detriment of United States industry.

Indeed, the language of the PPAA, and the legislative history, make it clear that Congress specifically intended Section 271(g) to add a federal court remedy for process patent owners. They also make it clear that Congress did not intend to subtract from the preexisting rights of process patent owners, including, specifically, the right to seek Exclusion Orders from the ITC against continued importation of products made abroad by infringing processes. Again, AIPLA believes that this considered decision is correct and should not be changed in a manner that would undermine the longstanding rights of United States process patent owners and place them at a disadvantage relative to their foreign competitors.

The proposed amendment to Section 271(g) would be detrimental to United States manufacturers. The proposed amendment would put domestic manufacturers at a competitive disadvantage relative to their foreign competitors. A domestic manufacturer has no defense to

infringement of a United States process patent under 35 U.S.C. § 271(a) on the grounds that its product made in the United States by a patented process will later be "materially changed by subsequent processes" or "become[s] a trivial and nonessential component of another product." Yet its foreign competitors would not face this problem. The practice outside the United States of a process protected by a U.S. patent is not an infringement of the U.S. patent. There is no § 271(a) action that can be brought against a foreign company for activity outside the United States. If the proposed amendment were adopted, a company in China could take the next step in the manufacturing cycle and transform an intermediate compound (produced according to a patented process) into a chemically-different final product, and import it with impunity into the United States. Or a company in Russia could produce a new heat-resistant alloy according to a patented process, use the resulting alloy to manufacture bearings, and freely import the bearings into the country as a trivial component of massive turbines for power generation. Or a company in South Korea might employ a patented method for forming conductive lines on semiconductor wafers as an initial step in manufacturing integrated circuits for use in cell phones that could be imported into the United States under either defense. Protecting American intellectual property against foreign usurpation is already difficult; the amendment would make it more so.

Moreover, the amendment would create a perverse incentive to offshore domestic manufacturing and jobs. If the defenses to infringement of United States process patents were made applicable to Section 337, they could provide an incentive for domestic manufacturers to practice patented manufacturing processes offshore in order to take advantage of those defenses in the same manner as their foreign competitors. Given the existing pressures to offshore American jobs to countries with low cost labor, aiding their exodus by weakening protection for U.S. process patents would seem unwise.

Conclusion

For these reasons, AIPLA opposes any amendment to Section 271(g) to create new defenses in Section 337 proceedings in the ITC that would only benefit foreign manufacturers accused of unfair trade practices. We do not believe Section 337 should be amended in a manner that would benefit foreign manufacturers at the expense of American patent owners, manufacturers, and workers.

Statement of Senator Leahy Chairman, Senate Judiciary Committee Hearing on "Process Patents"

May 1, 2007

A few weeks ago, I joined with Senator Hatch and other Senators, and with Chairman Berman and Representative Smith from the House Judiciary Committee, to introduce sweeping bipartisan, bicameral patent reform legislation. We are working to update our patent laws to provide much-needed reform for patent seekers and patent holders. The Supreme Court is also more engaged in patent law decisions than it has been in decades, having decided three important cases already this term. In two decisions released just yesterday, the Supreme Court ventured first into the fundamental issue of the standard for "obviousness" that would prevent patentability, and second spoke to the extraterritorial effect of U.S. patent laws.

In the process of drafting our patent reform legislation, we heard a good deal about another issue involving U.S. patents and overseas manufacturing -- the issues surrounding products produced overseas using processes patented in the United States. One of those issues is the importation of these products. Today, we turn to the debate about what defenses should be available to a party accused of importing products manufactured abroad by infringing a U.S. process patent. Those who work in this area refer to this issue as the "271(g) question."

It is often the case that litigation brings important issues to our attention in Congress. It should always be the case that we do not intend to interfere with that litigation. Well aware that private parties are interested, the Committee proceeds today careful to limit the considerations of this issue to those of public policy.

Prior to Congress's amending the patent laws in 1988, a company holding a U.S. process patent could sue for infringement of that patent only if the infringement took place within the United States. If the infringement took place overseas, the patent holder's only recourse was to the International Trade Commission (ITC) to exclude the product from the U.S. market. In 1988, Congress amended the law to permit patent holders to sue in federal court for patent infringement when a product, produced abroad using a process patented in the U.S., is imported or offered for sale in the U.S. This action, however, was subject to defenses created for patent infringement cases in which the product being imported was substantially altered.

The ITC has held that these "271(g)" defenses are not available in ITC exclusion proceedings because the plain language of the statute, confirmed by legislative history, applies them only to patent infringement claims being considered in federal court pursuant to the 1988 amendment. The issue we consider today is whether this distinction should remain.

I have heard from those who argue that the defenses were never intended to be limited to infringement claims, and the law should be changed to harmonize ITC and district court

litigation. Others argue that the purposes of an ITC exclusion proceeding and district court patent infringement litigation are simply different. If we permit products to enter the United States that were made abroad by a process patented here – where creation of the product would itself be an act of infringement if it occurred here – we are doing nothing less than outsourcing infringement and offshoring jobs.

This may seem like is a very narrow legal issue but the policy that will animate our decision can have a very wide reach. Congress should be fully informed. I look forward to the testimony of our witnesses today, and appreciate their assistance as we try to find the best way forward.

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Process Patents
Before the Senate Judiciary Committee
May 1, 2007

John R. Thomas*
Professor of Law
Georgetown University

Chairman Leahy, Ranking Member Specter, and Members of the Committee: Thank you for this opportunity to appear before you to discuss the Patent Reform Act of 2007. I testify here on my own behalf, and my views are not necessarily those of any institution with which I am associated.

The issue before the Committee unquestionably involves a great deal of intellectual property arcana. Even for many patent attorneys the issue is obscure. In the view of many observers, however, the question at issue reduces to an elemental proposition of a just system of laws: That like cases should be decided alike, regardless of the forum in which the case is heard.[1] This issue also potentially implicates the ability of the U.S. patent enforcement regime to achieve congressional objectives, the availability of high technology products to U.S. consumers, and the compliance of the United States with its international obligations. As a result, the current fragmented enforcement regime associated with process patents is well worth further consideration by the 110th Congress.

The Enforcement of Process Patents

When a patent claim is expressed as a series of steps, it is known as a method or process claim.[2] Traditionally the patent law held that a process claim could be directly infringed only by the

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[1] *See* John M. Eden, *Unnecessary Indeterminacy: Process Patent Protection After* Kinik v. ITC, 2006 DUKE L. & TECH. L. REV. 9; Ann Elise Herold Li, *Is the Federal Circuit Affecting U.S. Treaties? The ITC, § 271(g), GATT/TRIPS and the* Kinik *Decision*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 601 (2006).

[2] John R. Thomas, *Of Text, Technique and the Tangible: Drafting Patent Claims Around Patent Rules*, 17 JOHN MARSHALL J. COMPUTER & INFO. L. 219 (1998).

performance of those steps within the United States.[3] Congress has enacted two statutes that modify this principle, however. Each of these statutes allow U.S. patent holders to prevent foreign manufacturers from practicing their proprietary processes abroad; and then importing the product of that process into this country.

The first of these statutes was the Tariff Act of 1930, as amended through subsequent legislation. That statute makes it unlawful to import into the United States "articles that . . . are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent."[4] If the patent proprietor successfully seeks an exclusion order from the International Trade Commission (ITC), it may obtain a ban on imported products produced through the infringing process.

Alternatively, under the Patent Act of 1952, as amended by the Process Patent Amendments Act of 1988 (PPAA),[5] a patent holder may bring an action in federal district court against the importing manufacturer. The prevailing patentee in those circumstances may obtain an injunction against the importer, along with monetary damages to compensate for the infringement. As codified at 35 U.S.C. § 271(g), a number of exceptions limit liability under the PPAA. In particular, §271(g) provides that if the product is materially changed by subsequent processes, or becomes a trivial or nonessential component of another product, then there is no infringement.[6]

The *Kinik* Dicta

The 2004 opinion of the U.S. Court of Appeals for the Federal Circuit in *Kinik Co. v. International Trade Commission* has resulted in controversy over the scope of protection afforded process patents.[7] The *Kinik* case involved the 3M Corporation's claims that the Kinik Company was importing products into the United States from Taiwan that were made through use of 3M's patented process. The Federal Circuit resolved the litigation by concluding first, that the ITC had not properly

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[3]United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127-28, 212 USPQ 889, 895 (D.C. Cir.1981) ("A product patent gives the patentee the right to restrict the use and sale of the product regardless of how and by whom it was manufactured. A process patentee's power extends only to those products made by the patented process. . . . A process patent thus 'leaves the field open to ingenious men to invent and to employ other processes.' 1 A. Walker, Patents s 23 at 140 (2d Deller ed. 1964). . . . A sale of a product made by a patented process does not itself infringe the patent; it is the unauthorized use of the process that infringes the patent.").

[4]19 U.S.C. §1337(a)(1)(B)(ii) (2006).

[5]Pub. L. No. 100-418, 102 Stat. 1107 (1988).

[6]35 U.S.C. §271(g) (2006). *See* Eli Lilly & Co. v. American Cyanamid Co., 82 F.3d 1568, 1571, 38 USPQ2d 1705, 1707 (Fed. Cir.1996).

[7]362 F.3d 1359 (Fed. Cir. 2004).

construed the claims of the 3M patent, and second, that under a proper claim construction, the 3M patent was not infringed.[8]

Although apparently not necessary to resolve the dispute before it, the Federal Circuit also embarked upon an excursion in statutory interpretation. In addition to its noninfringement argument, Kinik asserted that its product was "materially changed by subsequent processes" beyond the alleged use of 3M's patented process. Although this defense is acknowledged within the Patent Act, the Federal Circuit concluded that the exceptions set forth in 35 U.S.C. § 271(g)(1) and (2) do not apply to proceedings under the Tariff Act. In support of its conclusion, the court of appeals observed that the legislative history of the Process Patent Amendments Act provided:

> There is no intention to impose any of these limitations upon owners of products or on owners of process patents in suits they are able to bring under existing law. Neither is there any invention for these provisions to limit in any way the ability of process patent owners to obtain relief from the U.S. International Trade Commission.[9]

The court of appeals further stated that it would apply *Chevron* deference in support of the ITC's conclusion that the exceptions identified in § 271(g) do not apply to exclusion actions.[10]

The *Kinik* dicta has attracted criticism. With respect to the language from the legislative history, one commentator has explained that "the most natural reading" of this language is simply an intention not to constrain the ability of patent holders to obtain exclusion orders from the ITC, even though similar relief was now available in the federal district courts.[11] Similarly, the notion that "these limitations [do not apply to] owners of products or . . . owners of process patents in suits they are able to bring under existing law" suggests that the two exceptions do not apply to charges of process patent infringement in other, wholly domestic situations.

The application of *Chevron* deference has also been critiqued. According to one commentator, "after the Process Patent Amendments Act was passed in 1988, the ITC consistently and openly recognized the general applicability of § 271(g) defenses in exclusion actions."[12] The ITC's apparently changing views suggest that deference may not be appropriate, particularly because

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[8] *Id.* at 1361.

[9] *Id.* at 1362-63 (citing S. Rep. No. 100-83 at 60-61).

[10] *See id.* at 1363 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 843 (1984)).

[11] *See* Eden, *supra* note 1, at *10.

[12] *Id.* at *13.

"the ITC is not the agency charged with interpreting the Patent Act."[13]

Consequences of the *Kinik* Dicta

Regardless of whether the Federal Circuit correctly construed the governing statutes in *Kinik* or not, recent scholarly commentary has urged Congress to address the fragmented enforcement regime that now exists for process patents in the United States.[14] This commentary has identified numerous complications that arise from varying enforcement possibilities between the ITC and the federal district courts.

First, Congress intended the two exceptions of the Process Patents Amendment Act to balance the traditional competing objectives that inform intellectual property policy: Encouraging the labors that result in innovation, on one hand, and disseminating the fruits of the labors to the public, on the other. The "materially changed" and "nonessential component" limitations both balance the interests of patent proprietors with follow-on innovators and also recognize the territorial nature of the patent instrument. These congressional intentions may not be achieved if the patent proprietor can readily select a forum where the two limitations upon § 271(g) simply do not apply.[15]

Second, our current fragmented enforcement policy may limit the access of U.S. consumers to innovative products. As one commentator explains, "[o]ne could argue that *Kinik* chafes against the interests of U.S. consumers, consumers who would benefit from having access to less expensive goods, including everything from medicines to automobile parts."[16]

Finally, the remedial disparity between the district courts and the ITC potentially favors domestic industry over foreign firms. Because the availability of an exclusion order is premised upon the existence of a domestic industry, "[t]here is a clear difference in the defenses available for foreign goods and importers thereof when compared to their domestic counterparts, potentially constituting a 'disguised restriction on trade.'"[17] Another commentator observes:

> *Kinik* also has implications for international relations. Since *Kinik* stands for the idea that the ITC can lawfully make it significantly harder for a defendant to establish a defense based on noninfringement in an exclusion dispute, the foreign business community is likely to view this as an instance of protectionism. After all, the ITC is a body that can unilaterally exclude foreign products from importation into

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[13] *Id.* at *19.

[14] *Id.* at 32; Li, *supra* note 1, at 647.

[15] Eden, *supra* note 1, at *22.

[16] *Id.* at *23.

[17] Li, *supra* note 1, at 636.

> the United States, a fact that will inevitably color foreign perception of the fairness of its procedures. More specifically, foreign business interests are likely to find unfair (and perhaps hypocritical) Kinik's refusal to extend § 271(g)'s defenses–defenses that all defendants have in U.S. federal courts–to exclusion actions given the aggregate effect of exclusion orders on the balance of trade in intellectual property. Foreign businesses are likely to find this policy unfair (and perhaps hypocritical) . . . .[18]

Although the analysis of whether the current situation constitutes a violation of the TRIPS Agreement is complex,[19] the perceived favoritism for U.S. industry over foreign firms may send a conflicting message as the United States proceeds against Israel,[20] China,[21] and other trading partners for perceived lapses in their intellectual property regimes.

Conclusion

Since at least the publication of Artistotle's *Nicomachean Ethics*, the notion that like cases should be treated alike has been viewed as central to the notion of justice.[22] The disparate results available to process patent holders in the ITC, as compared to the district courts, has been broadly viewed as violating this fundamental norm of equivalence. Because these dissimilar rules of law potentially conflict with congressional intent, limit competition, and portray the United States in a negative light, academic commentary has expressed "hope that Congress will soon step in to ensure that the fragmented enforcement regime *Kinik* endorses is dismantled sooner rather than later."[23]

I look forward to hearing the view of my fellow witnesses on today's panel, and to answering any questions that may be presented. Thank you.

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[18]Eden, *supra* note 1, at *24.

[19]*See* Li, *supra* note 1, at 635-40.

[20]United States Trade Representative, *2004 Special 301 Report Watch List* (May 3, 2004) (available at www.ustr.gov).

[21]*See* United States Trade Representative, *United States Files WTO Cases Against China Over Deficiencies in China's Intellectual Property Laws and Market Access Barriers to Copyright-Based Industries* (April 9, 2007) (available at www.ustr.gov).

[22]ARISTOTLE, NICOMACHEAN ETHICS (trans. W. C. Ross) (available at http://classics.mit.edu/Aristotle/nicomachaen.html).

[23]Eden, *supra* note 1, at *32.

UNITED STEELWORKERS
USW
UNITY AND STRENGTH FOR WORKERS

Leo W. Gerard
International President

February 6, 2007

VIA FAX

Honorable Patrick Leahy, Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

Honorable Arlen Specter, Ranking Member
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senators:

The United Steelworkers (USW) represents over 850,000 members in the paper, forestry products, steel, aluminum, tire and rubber, mining, glass, chemicals, petroleum, and other basic resource industries, as well as health care and service workers. We are the predominant union in the pharmaceutical industry representing 15,000 members in manufacturing, mail-order, and retail pharmacies.

The Steelworkers are a strong advocate for a robust economy based on growth. An important component of sustaining American jobs is a full and fair recognition of the rights of innovators in the form of intellectual property protection, including patents, copyrights and trademarks.

Especially important in preserving the rights of American workers is an intellectual property system that protects against unfair foreign imports. If the American patent system is changed to allow foreign manufacturers to compete with a U.S. manufacturer in a way that other U.S. manufacturers are prohibited from competing, then a perverse incentive would be created that would grow jobs abroad to the detriment of U.S. manufacturing jobs.

We urge you to oppose efforts to change U.S. patent law in any way that would treat (at the International Trade Commission) foreign infringers more favorably than we treat (in court) domestic manufacturers who infringe. This would simply exacerbate our imbalance of trade. Our economy would suffer and American jobs would be lost.

Congress has been asked by at least one foreign pharmaceutical manufacturer to weaken American process patent protection (Roll Call, March 20, 2006) at the ITC. We oppose this foreign manufacturer's efforts to weaken the ability of the ITC to enforce fair trade laws. As you consider broader patent reform, please keep any changes to 35 USC 271(g) out of any introduced patent reform bill, and please oppose any amendments that seek to add this language to any bill.

Much like the university community and others in the private sector, we firmly support current law, which enables the ITC to guard against unfair trade. The U.S. Congress should not change patent or trade law in such a way that domestic manufacturing jobs would be threatened by unfair foreign competitors whose actions would have been prohibited as infringement if they had been done in the U.S.

Sincerely,

Leo W. Gerard
International President

LWG/pak

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